US009554903B2

(12) United States Patent
Rowe et al.

(10) Patent No.: US 9,554,903 B2
(45) Date of Patent: *Jan. 31, 2017

(54) **RAPID DEPLOYMENT PROSTHETIC HEART VALVE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/571,141**

(22) Filed: **Dec. 15, 2014**

(65) **Prior Publication Data**

US 2015/0105856 A1 Apr. 16, 2015

Related U.S. Application Data

(63) Continuation of application No. 13/954,822, filed on Jul. 30, 2013, now Pat. No. 8,911,493, which is a

(Continued)

(51) **Int. Cl.**

A61F 2/24 (2006.01)
A61F 2/90 (2013.01)

(52) **U.S. Cl.**

CPC ***A61F 2/2418*** (2013.01); ***A61F 2/2409*** (2013.01); ***A61F 2/2412*** (2013.01); ***A61F 2/2445*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC A61F 2/24; A61F 2/2412; A61F 2/2415; A61F 2/2418

See application file for complete search history.

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(57) **ABSTRACT**

A heart valve prosthesis that can be quickly and easily implanted during a surgical procedure is provided. The prosthetic valve comprises a support structure that is deployed at a treatment site. The prosthetic valve further comprises a valve member configured to be quickly connected to the support structure. The support structure may take the form of a stent that is expanded at the site of a native valve. If desired, the native leaflets may remain and the stent may be used to hold the native valve open. In this case, the stent may be balloon expandable and configured to resist the powerful recoil force of the native leaflets. The support

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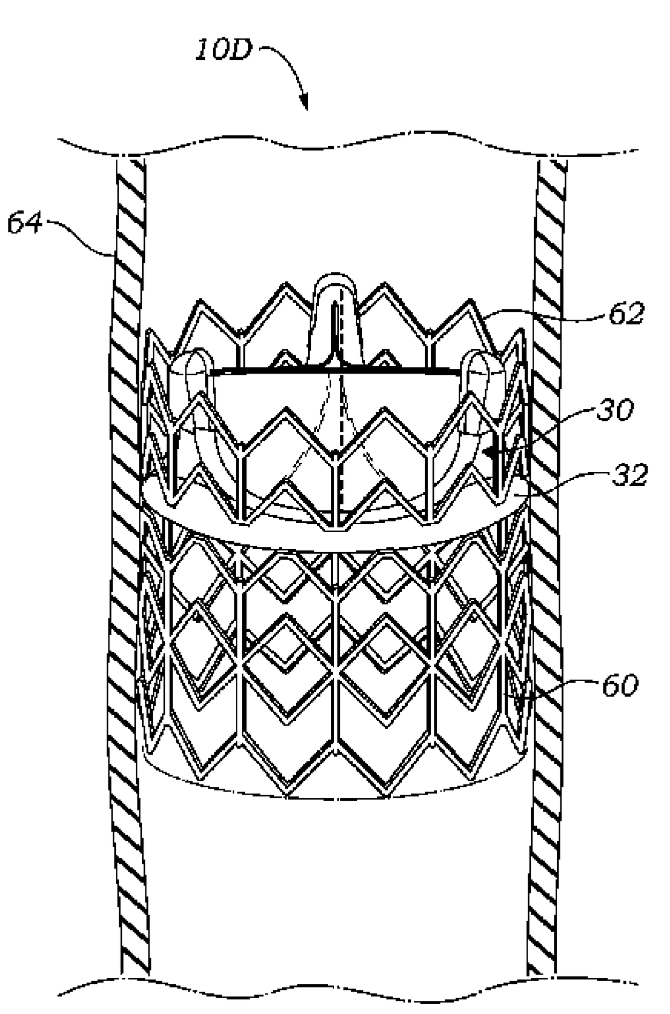

structure is provided with a coupling means for attachment to the valve member, thereby fixing the position of the valve member in the body. The valve member may be expandable or a non-expandable type.

9 Claims, 26 Drawing Sheets

Related U.S. Application Data

continuation of application No. 11/441,406, filed on May 24, 2006, now Pat. No. 8,500,798.

(60) Provisional application No. 60/684,443, filed on May 24, 2005.

(52) **U.S. Cl.**
CPC ***A61F 2/90*** (2013.01); *A61F 2220/0008* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2220/0025* (2013.01); *A61F 2220/0041* (2013.01); *A61F 2220/0066* (2013.01); *A61F 2220/0075* (2013.01); *A61F 2220/0083* (2013.01); *A61F 2230/0078* (2013.01); *A61F 2250/006* (2013.01)

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Fig. 1

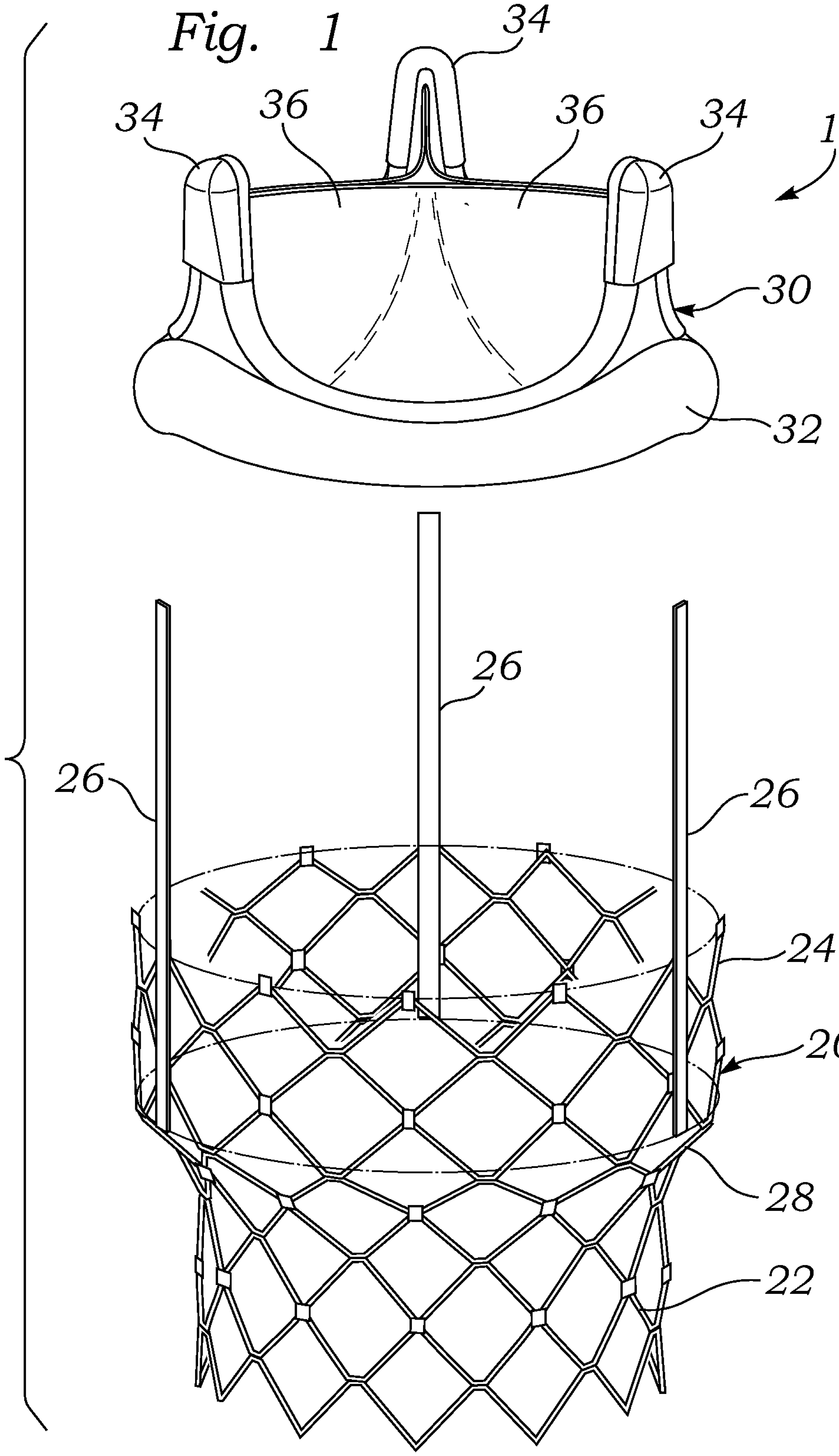


Fig. 2

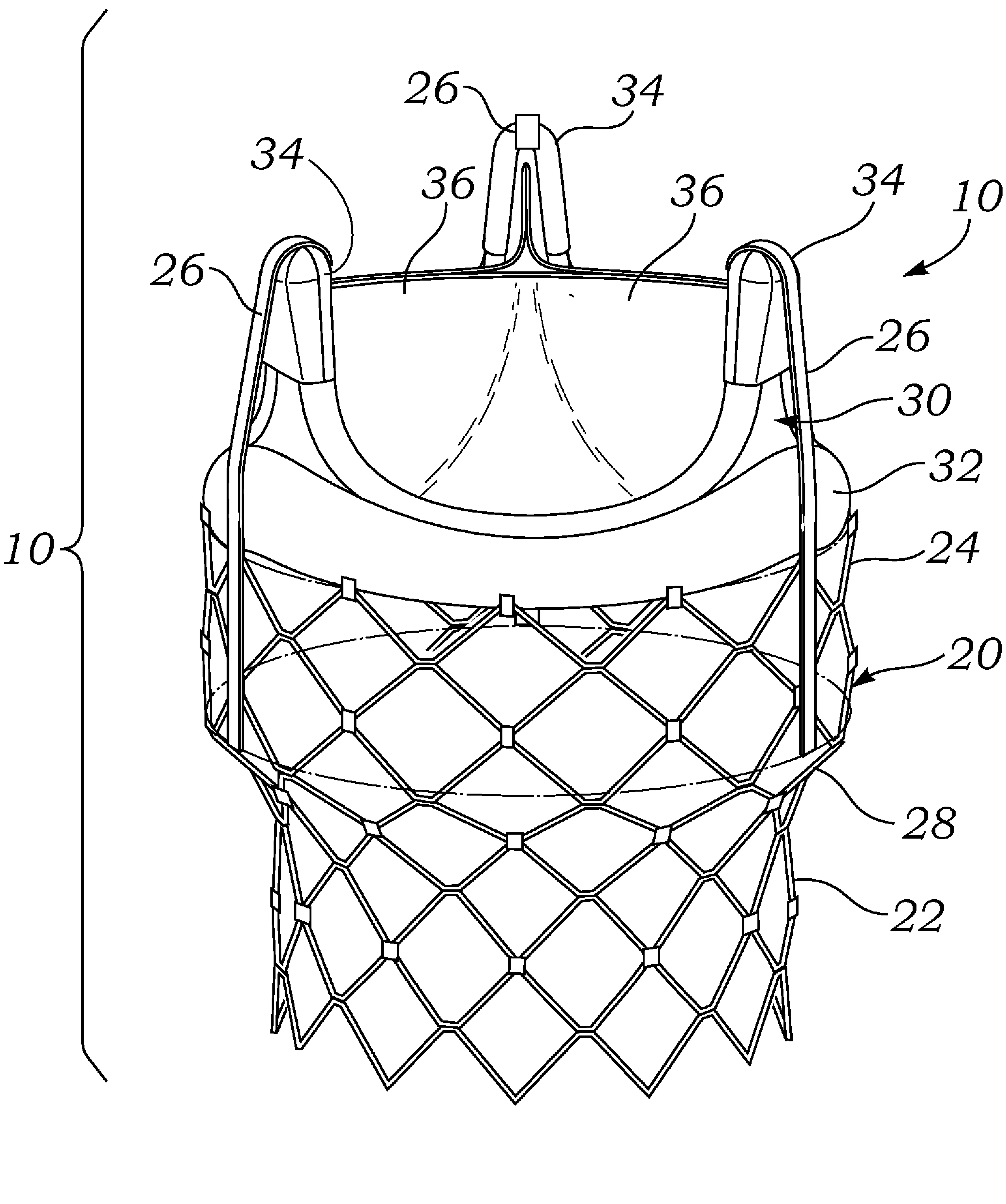


Fig. 3

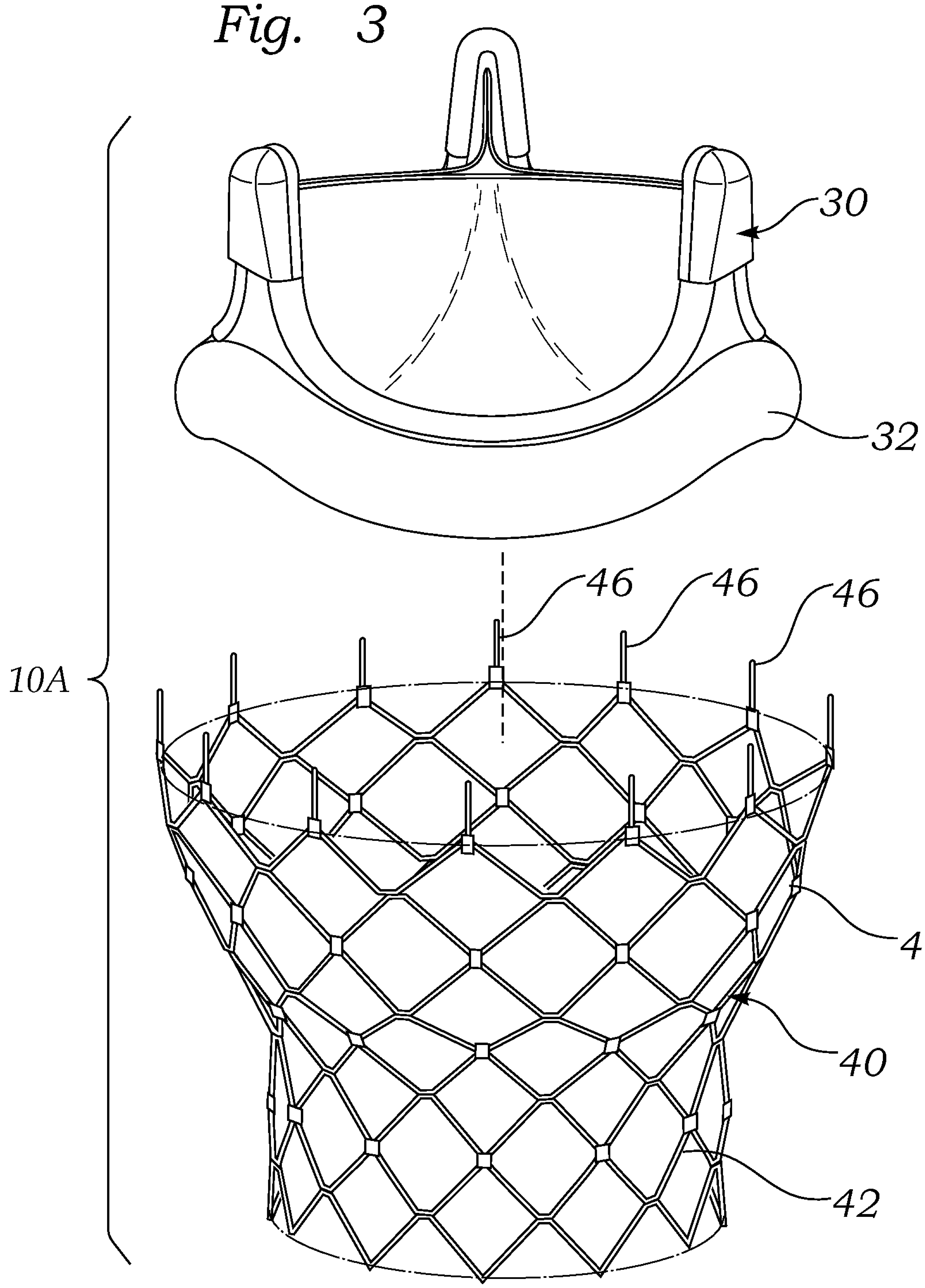


Fig. 4A

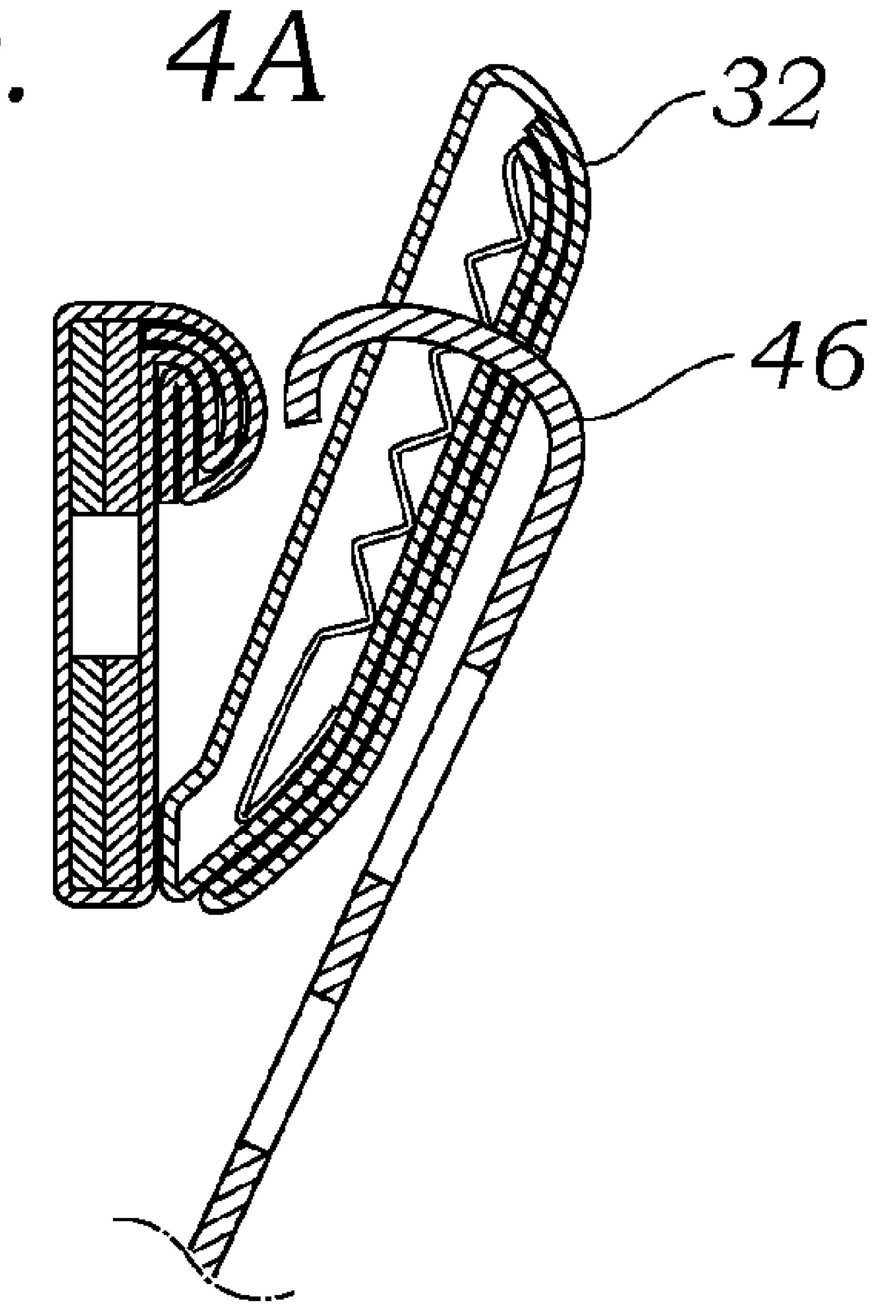


Fig. 4

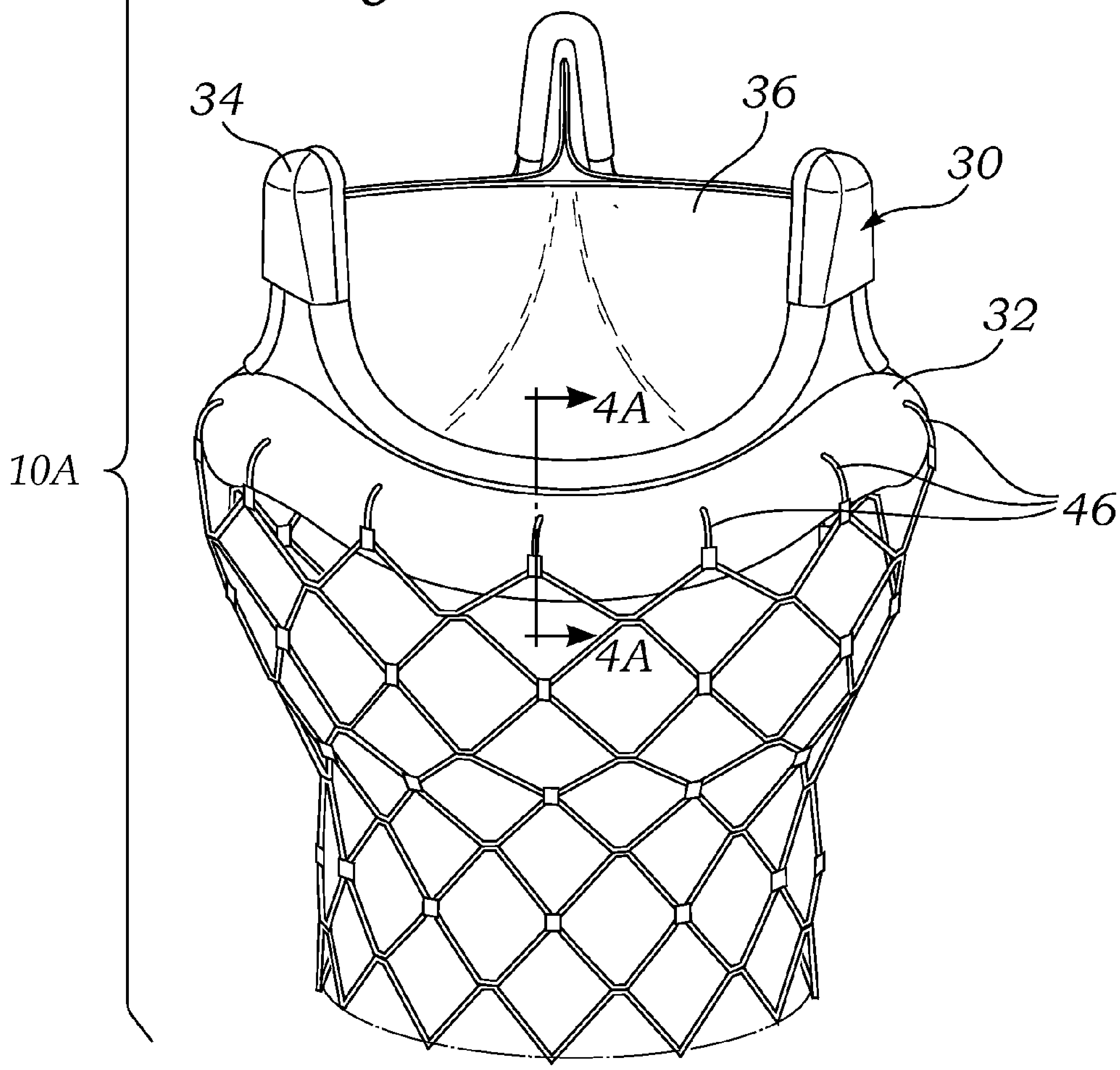


Fig.5A

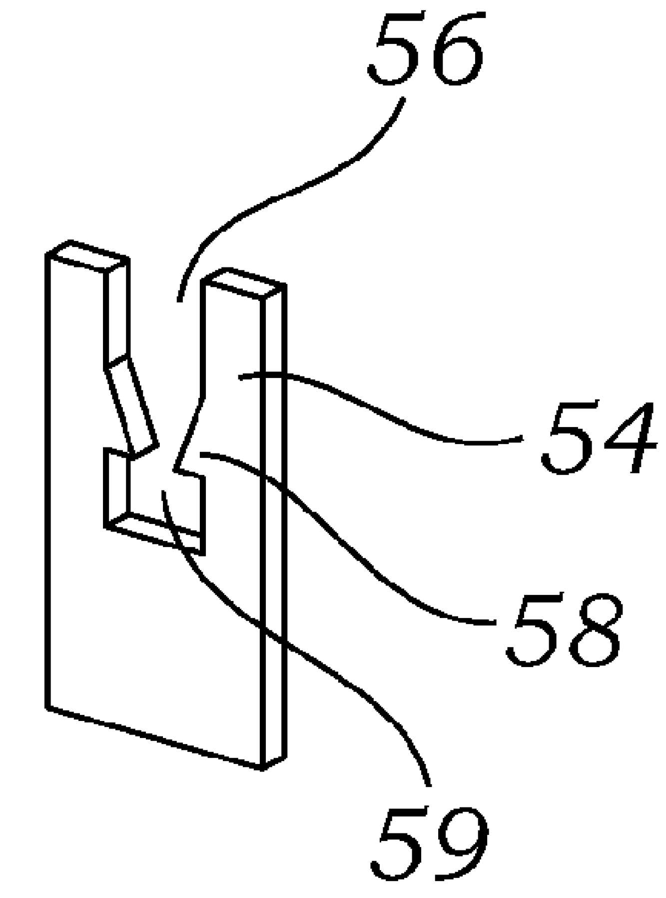


Fig.5

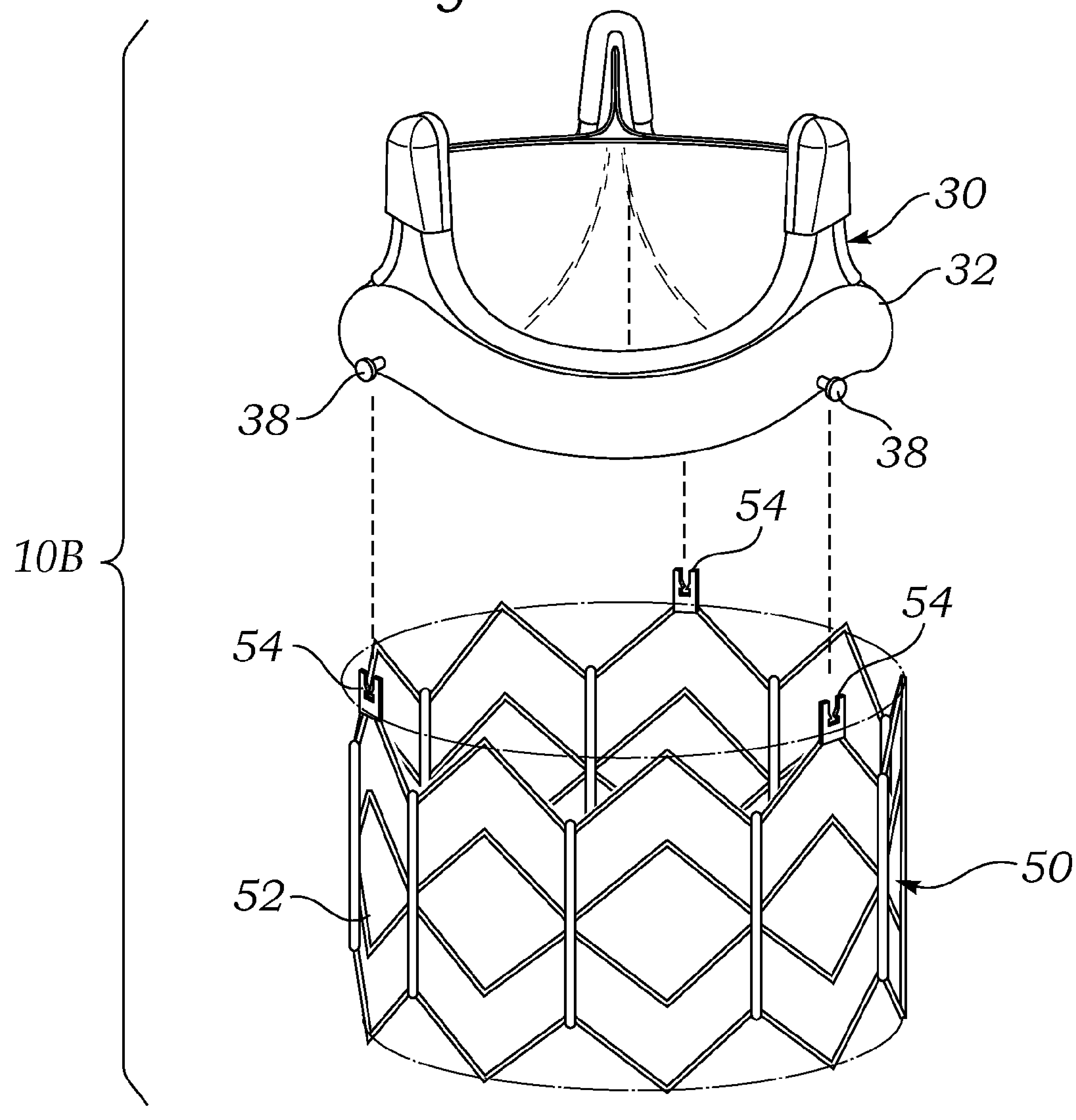


Fig. 6A

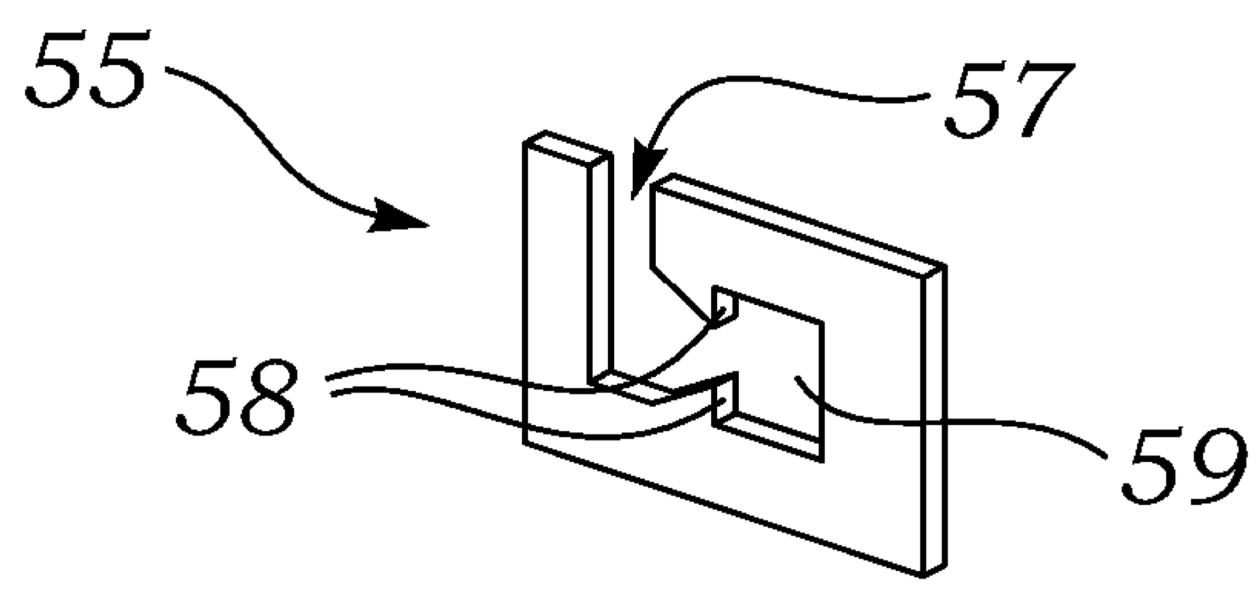


Fig. 6

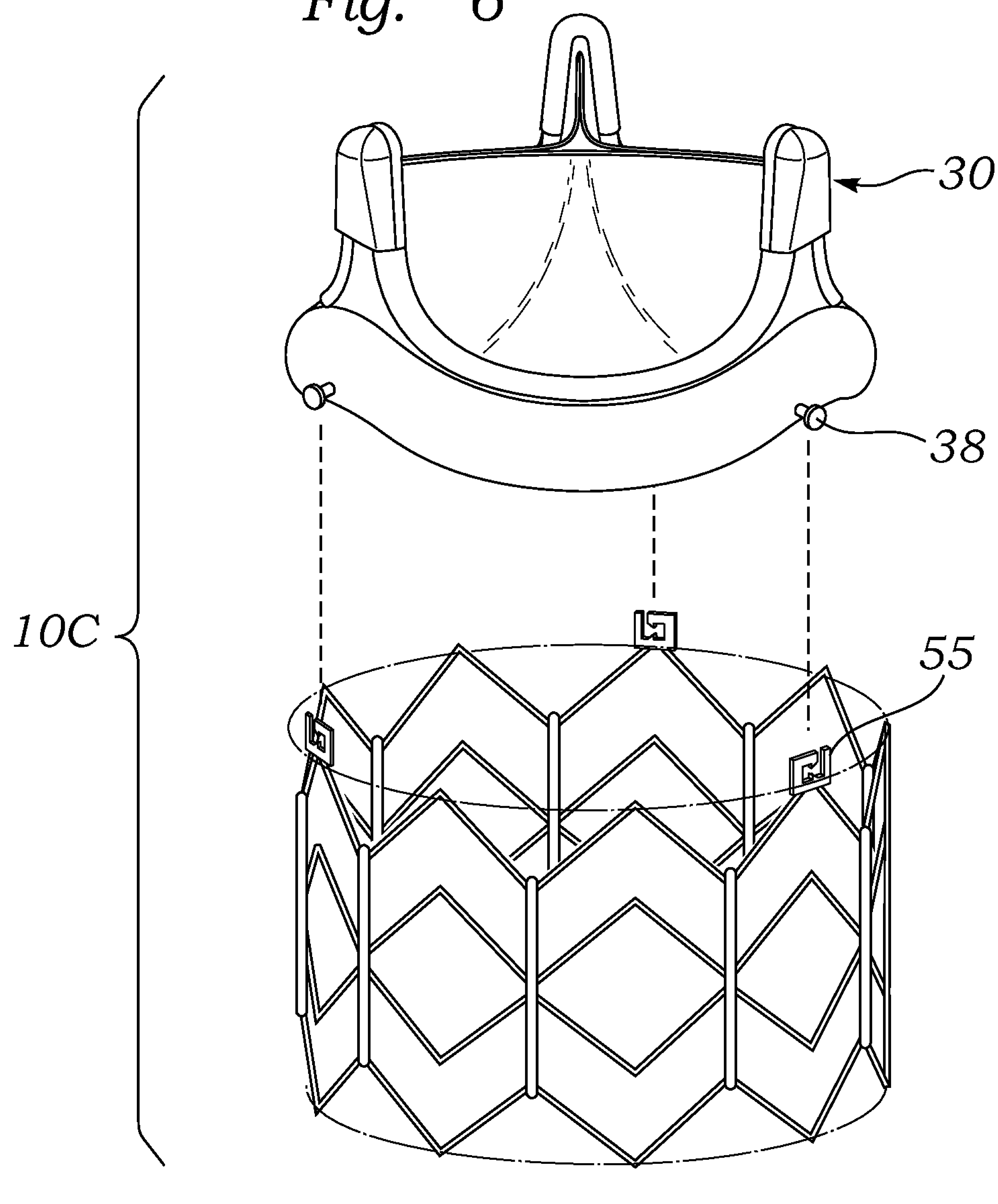


Fig. 7

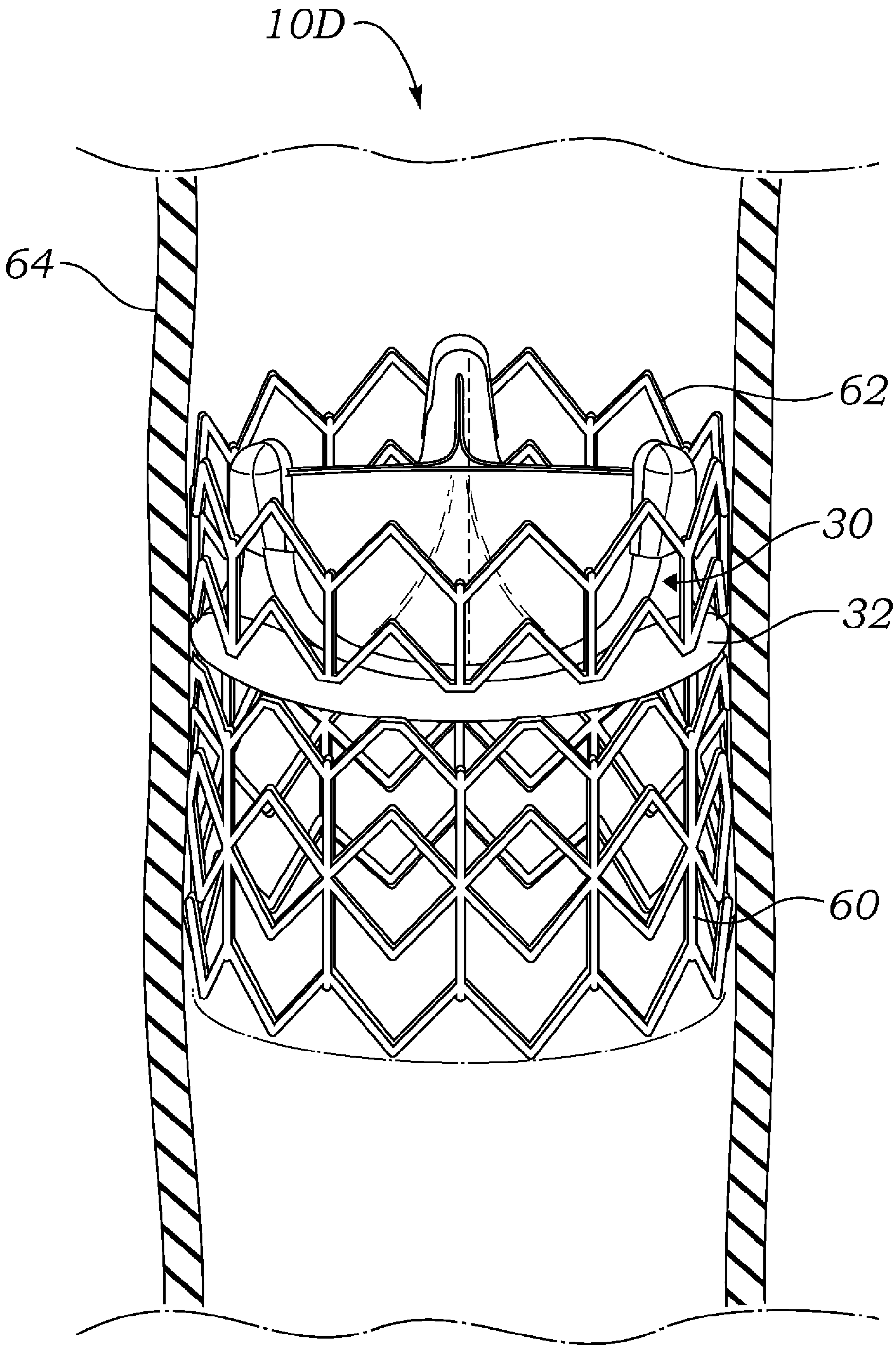
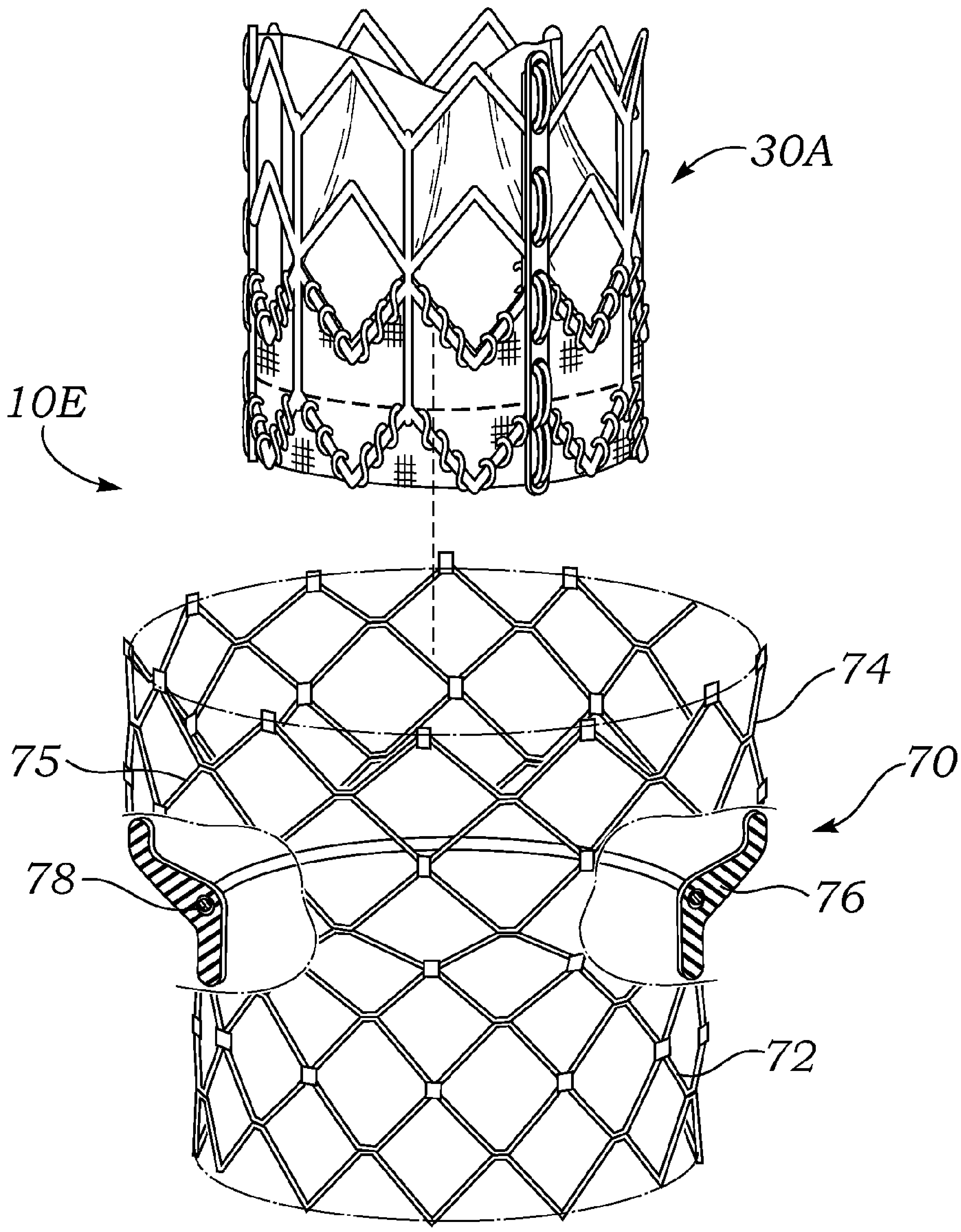


Fig.8



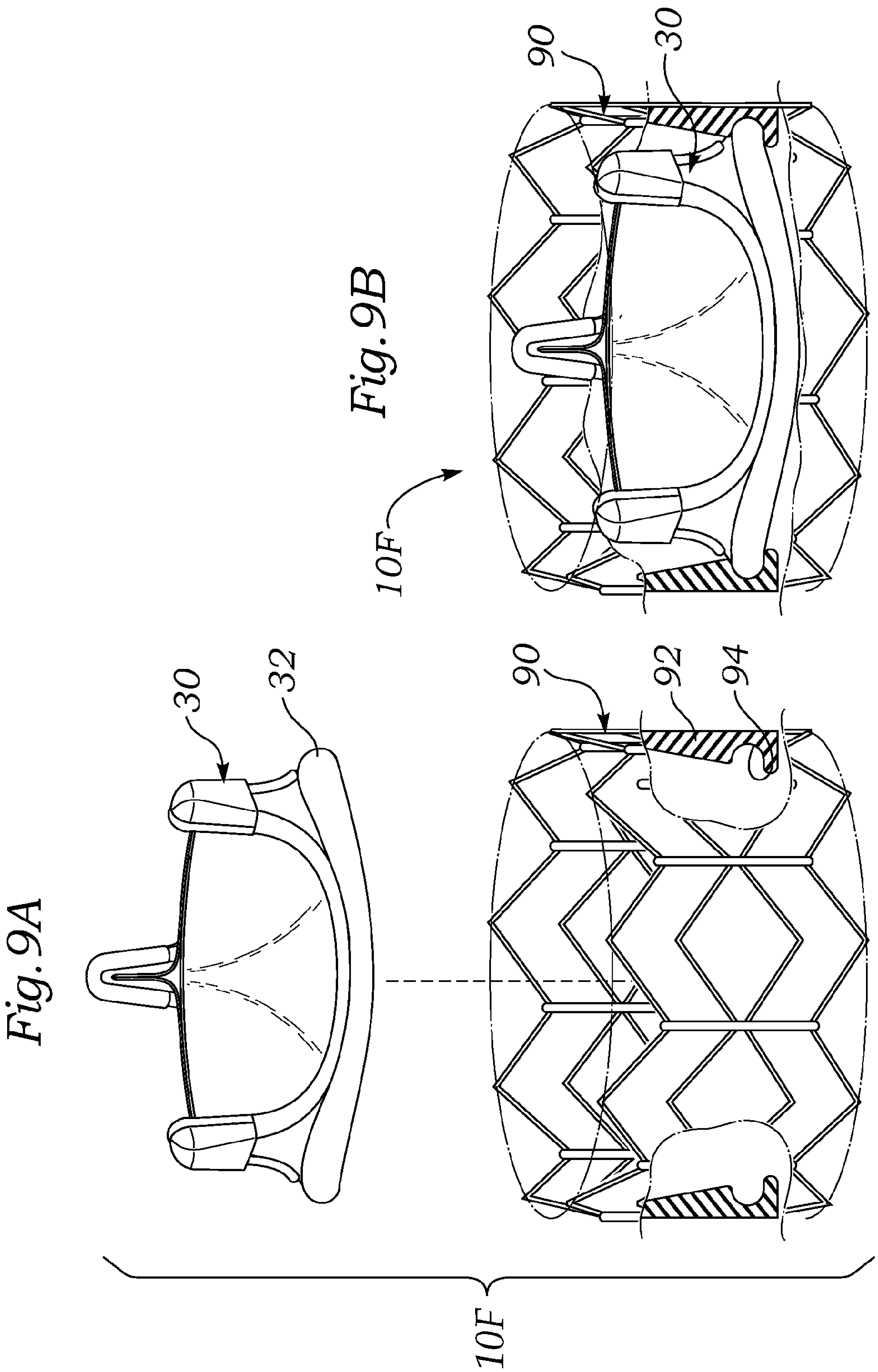


Fig. 9B

Fig. 9A

Fig. 10

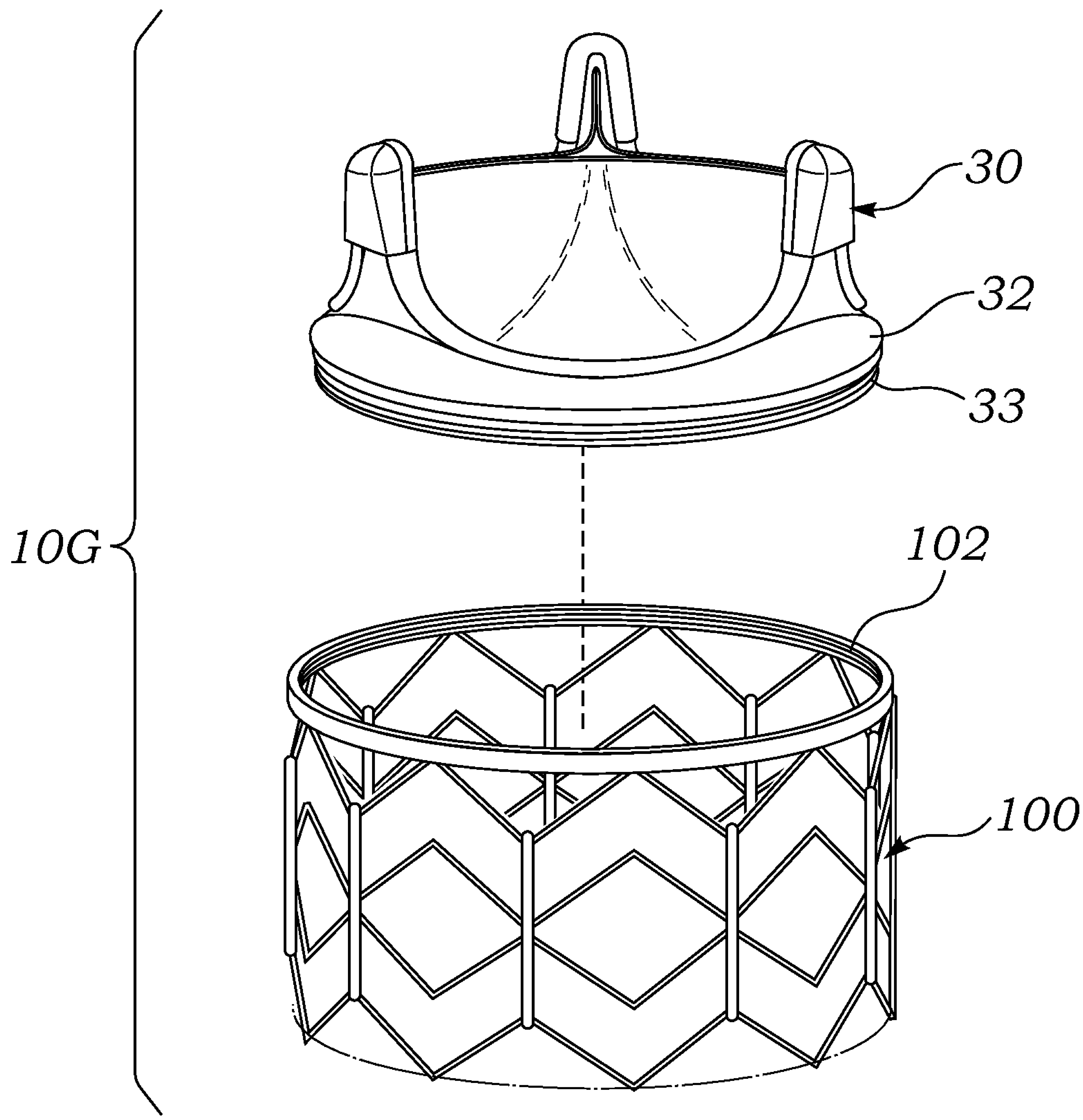
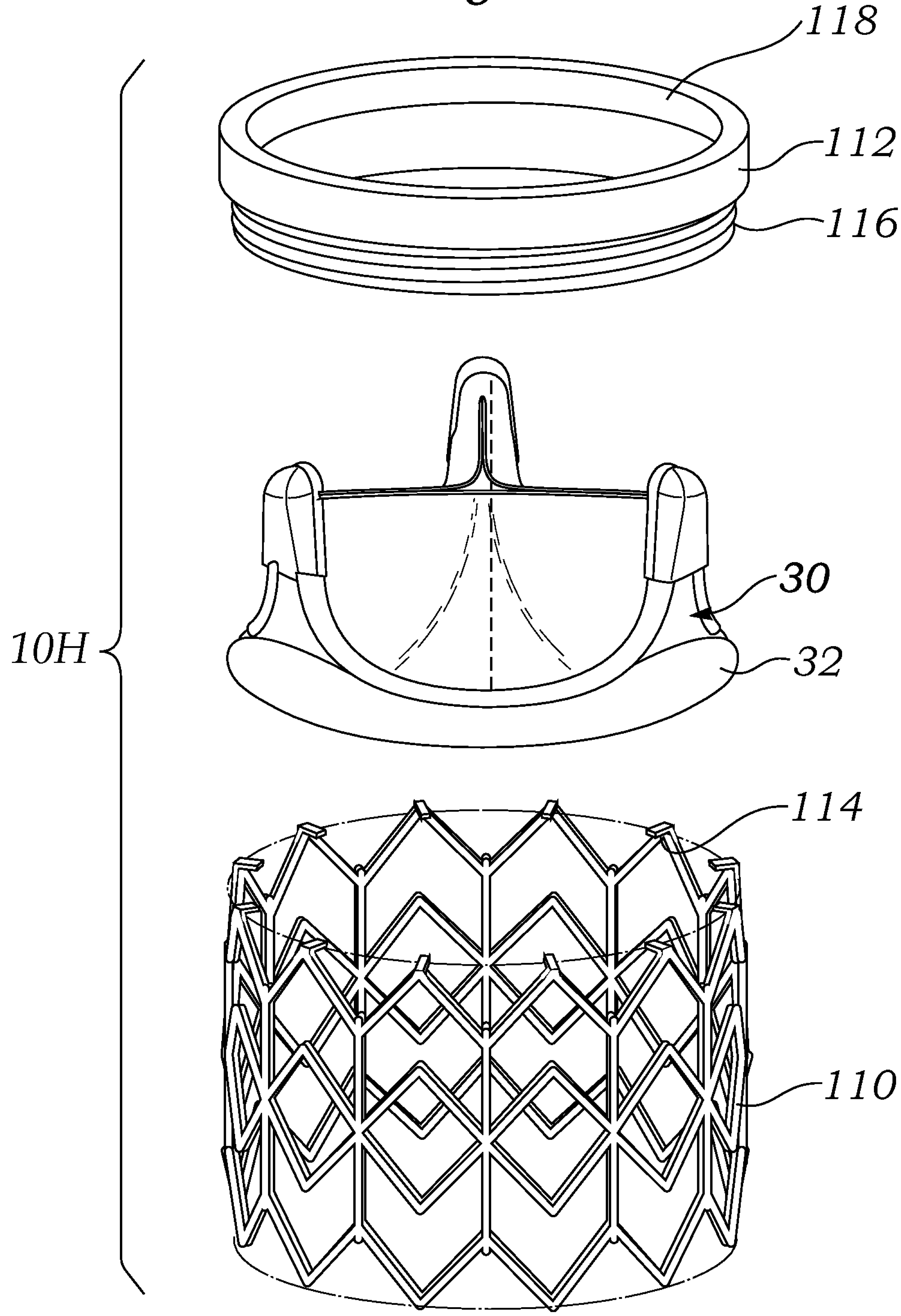


Fig.11



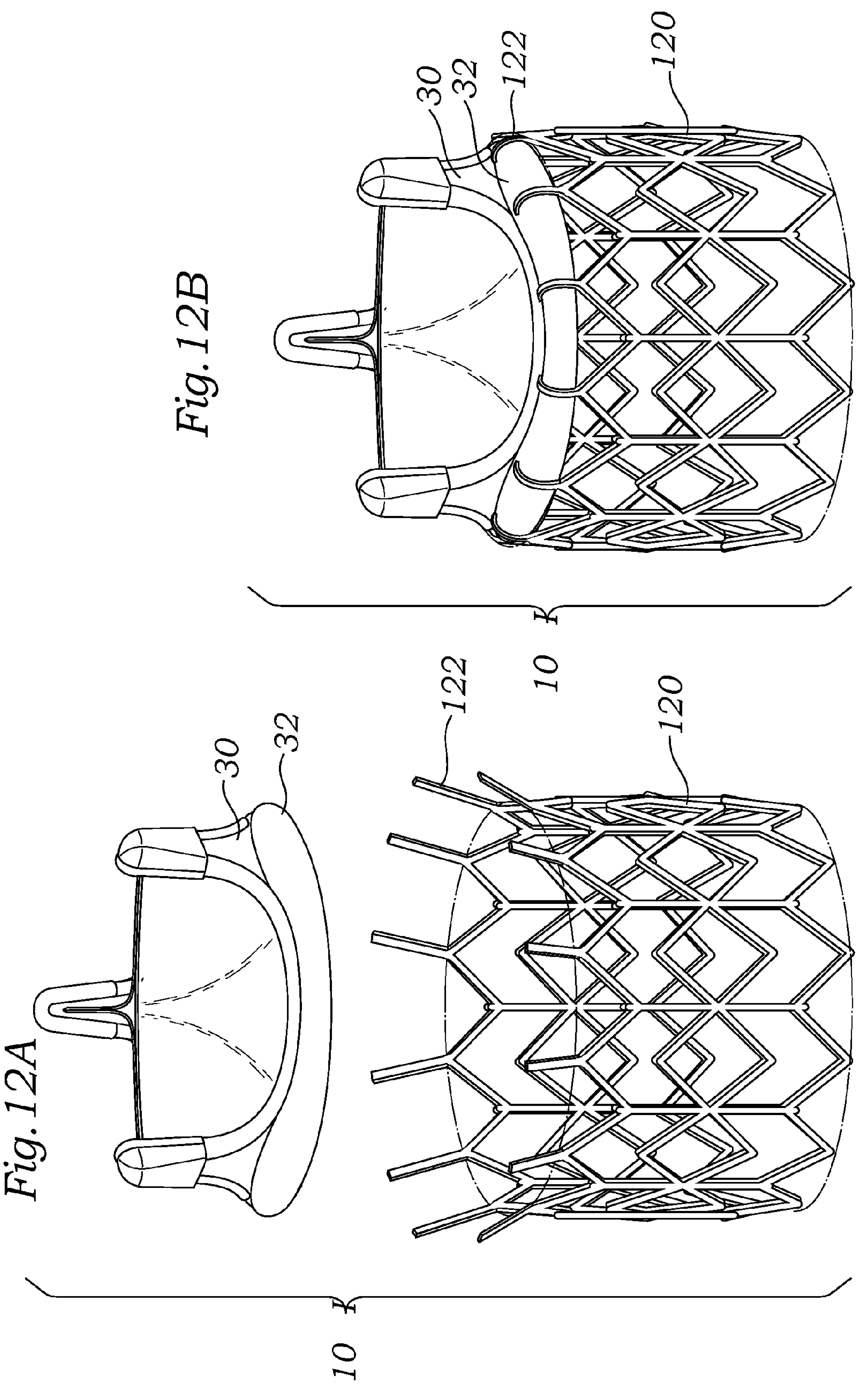


Fig. 12B

Fig. 12A

Fig. 12D

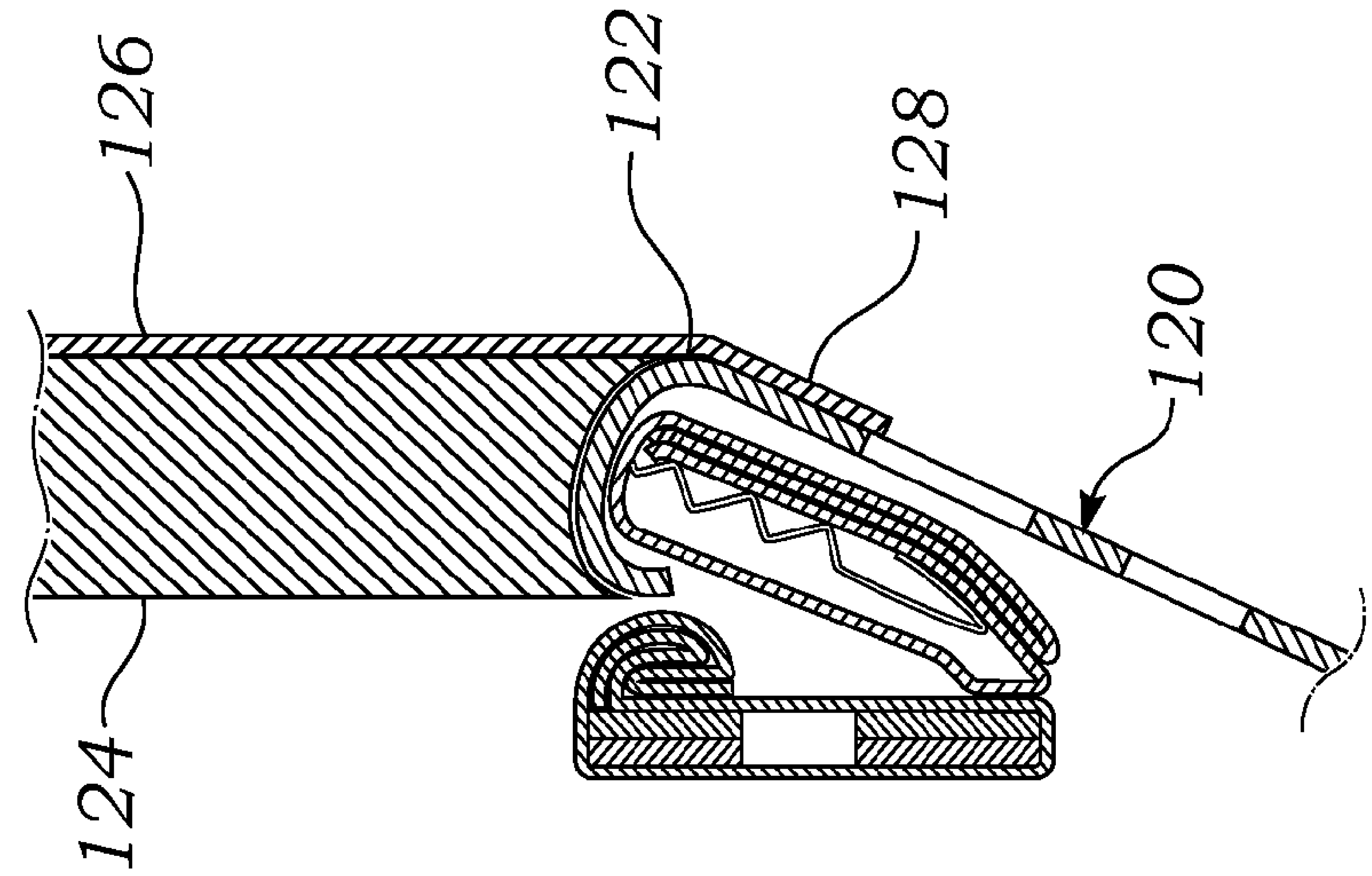


Fig. 12C

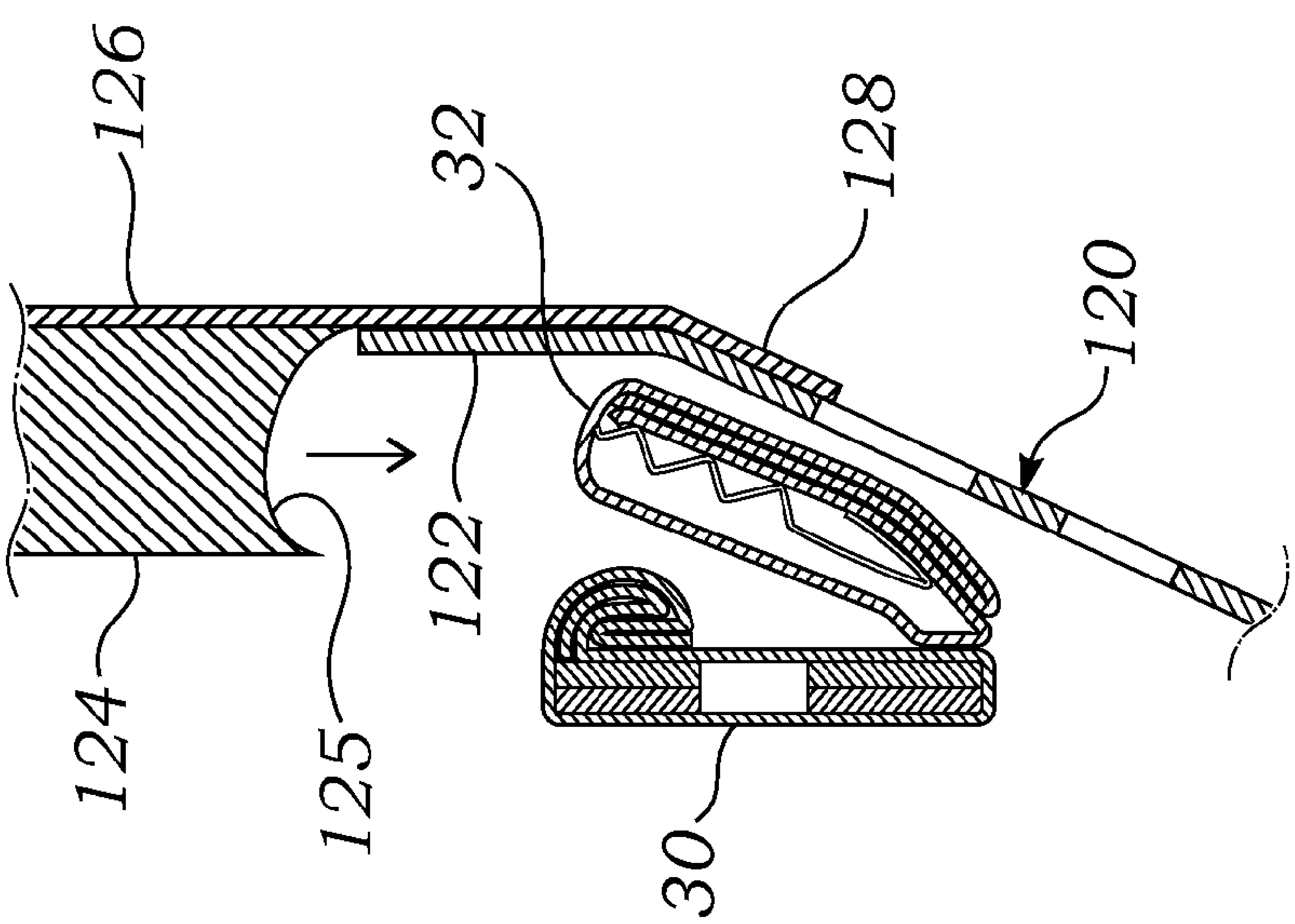


Fig. 13A

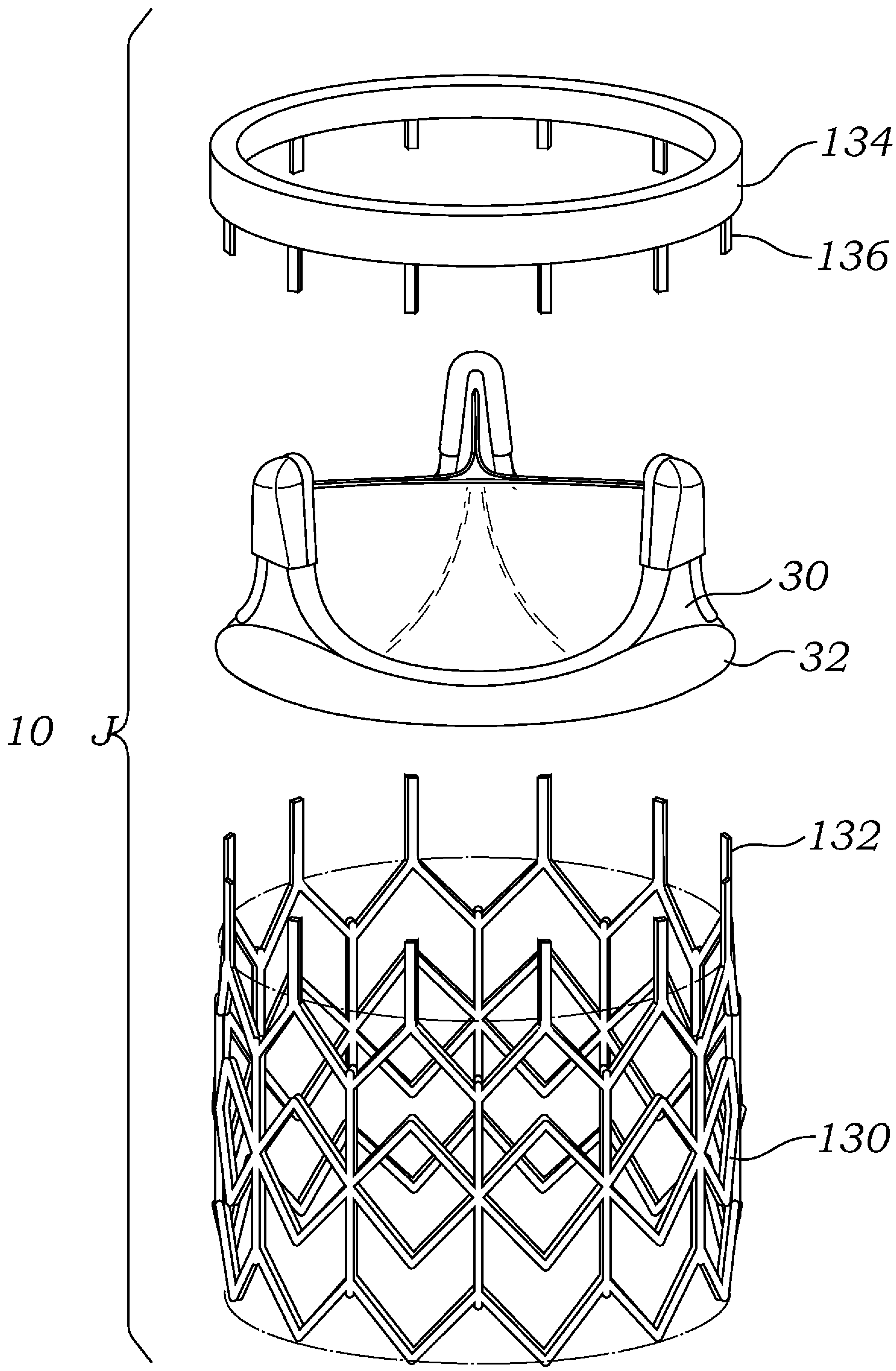


Fig. 13B

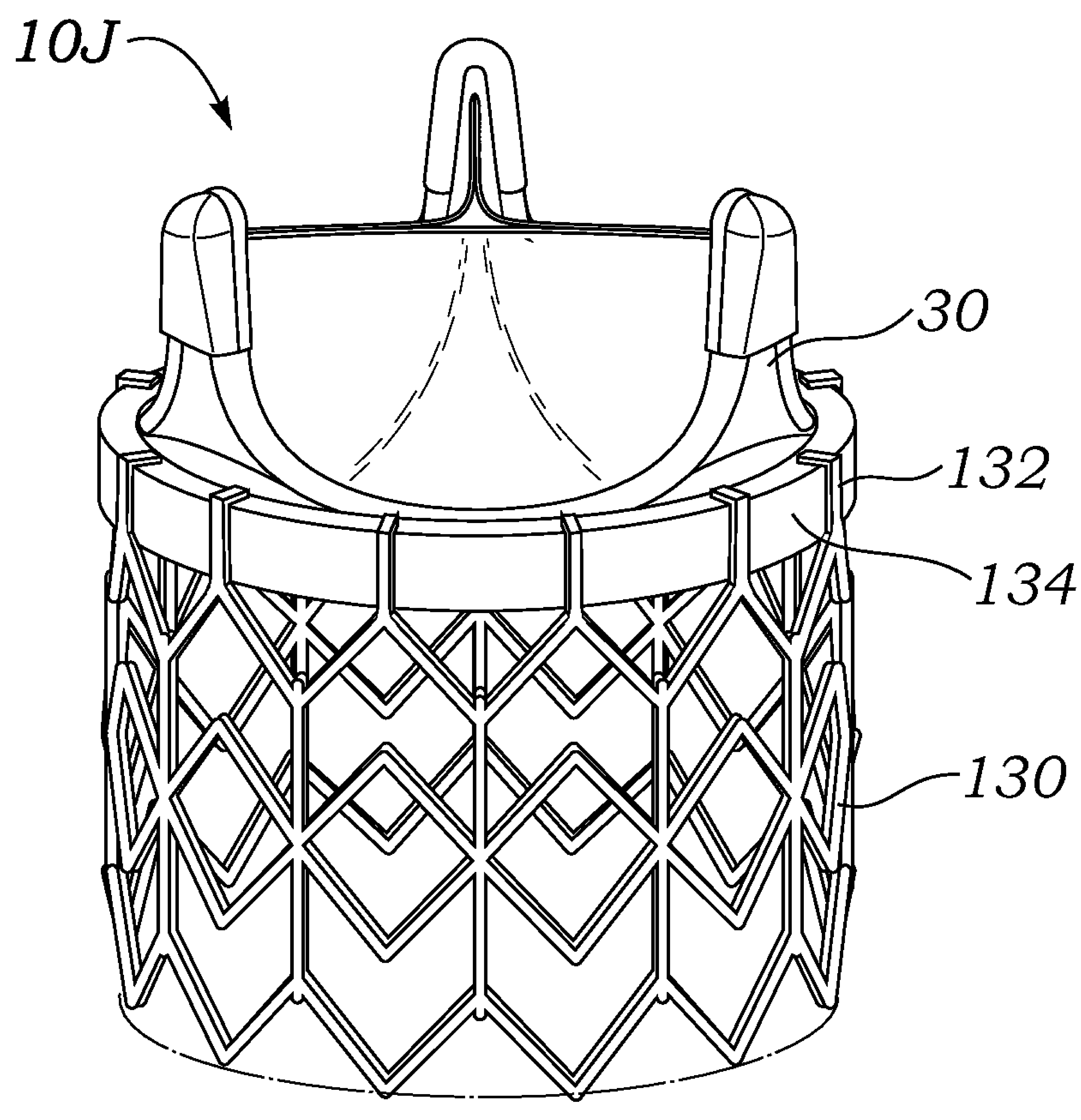


Fig. 14A

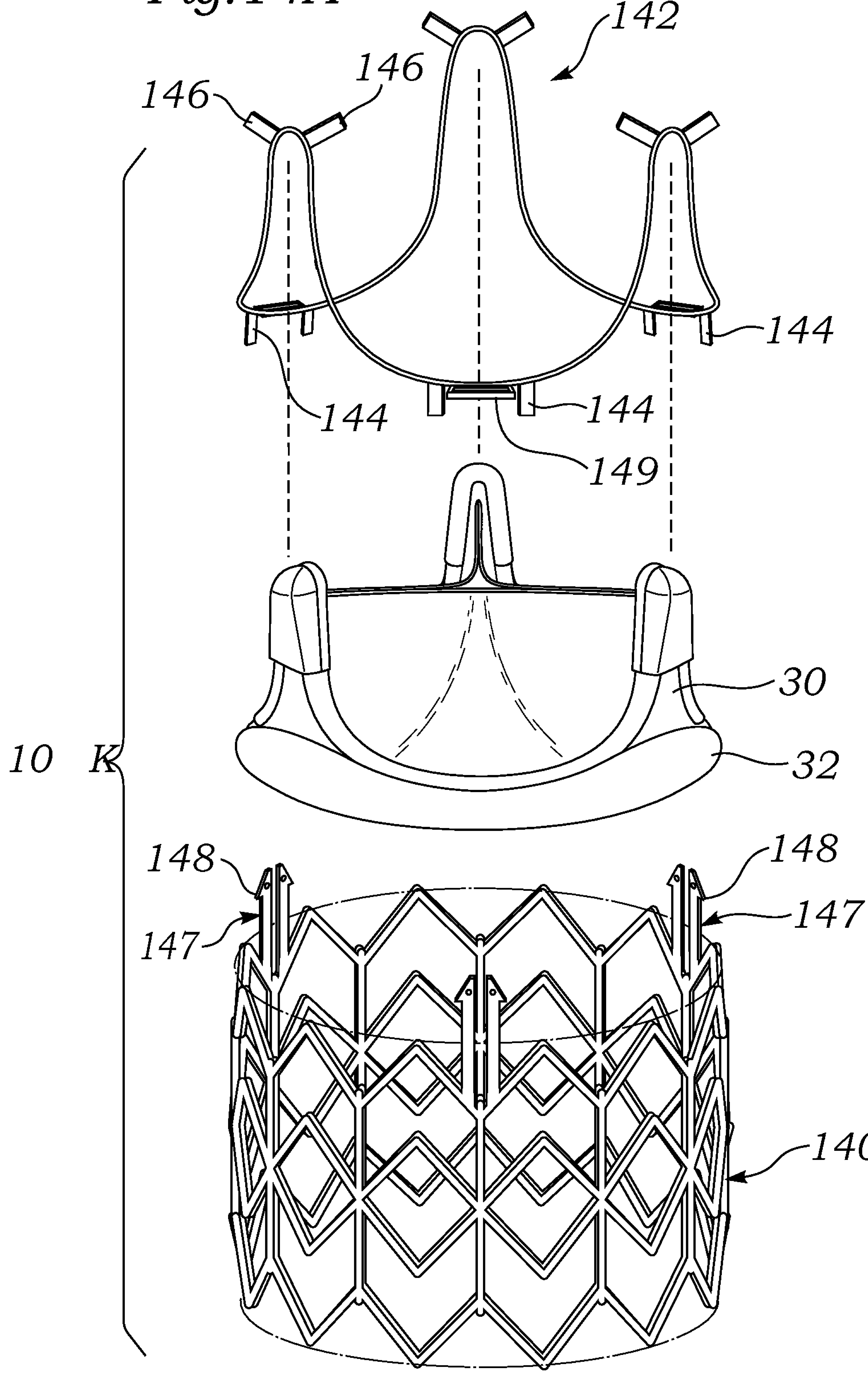


Fig.14B

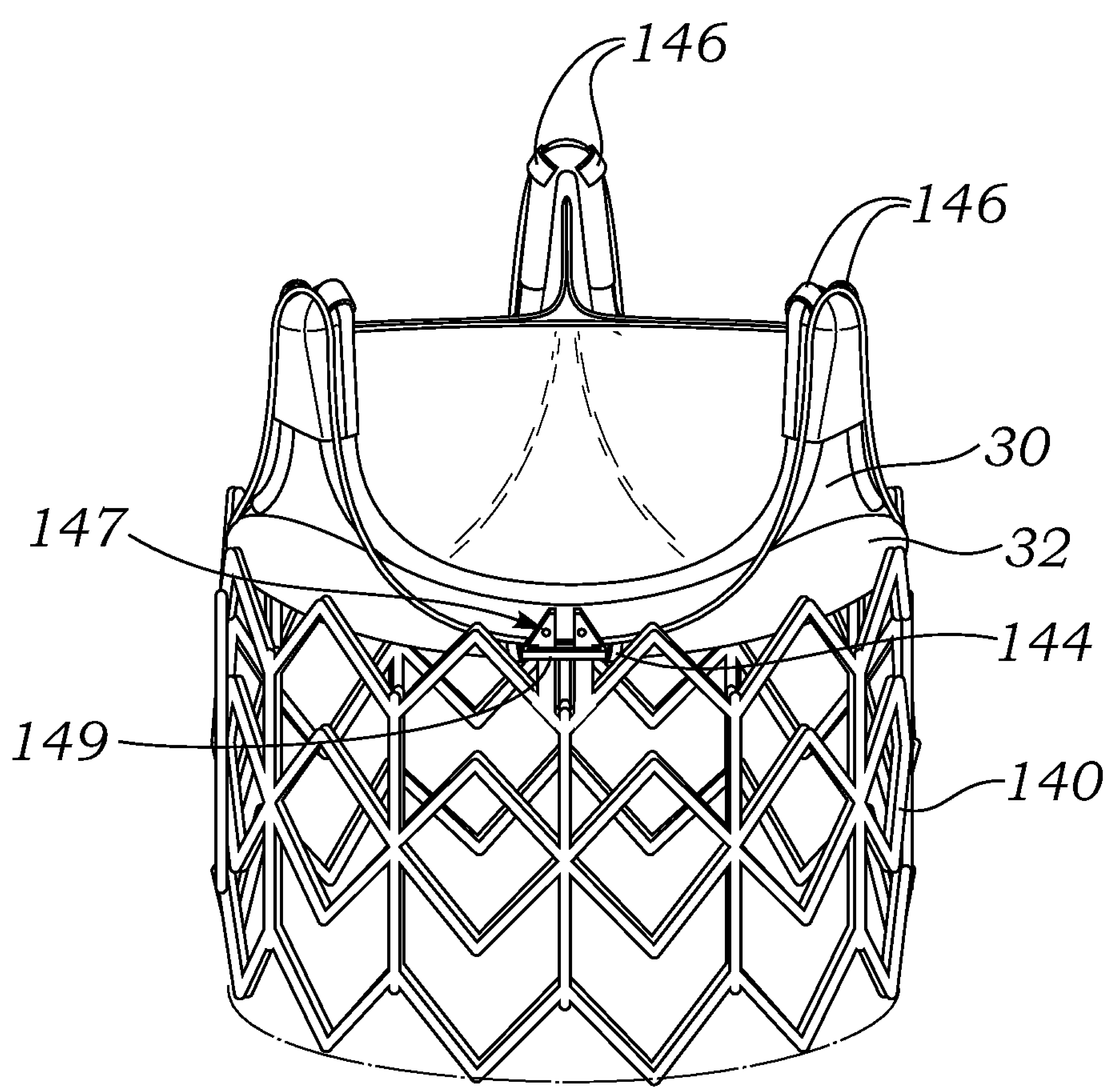


Fig. 15B

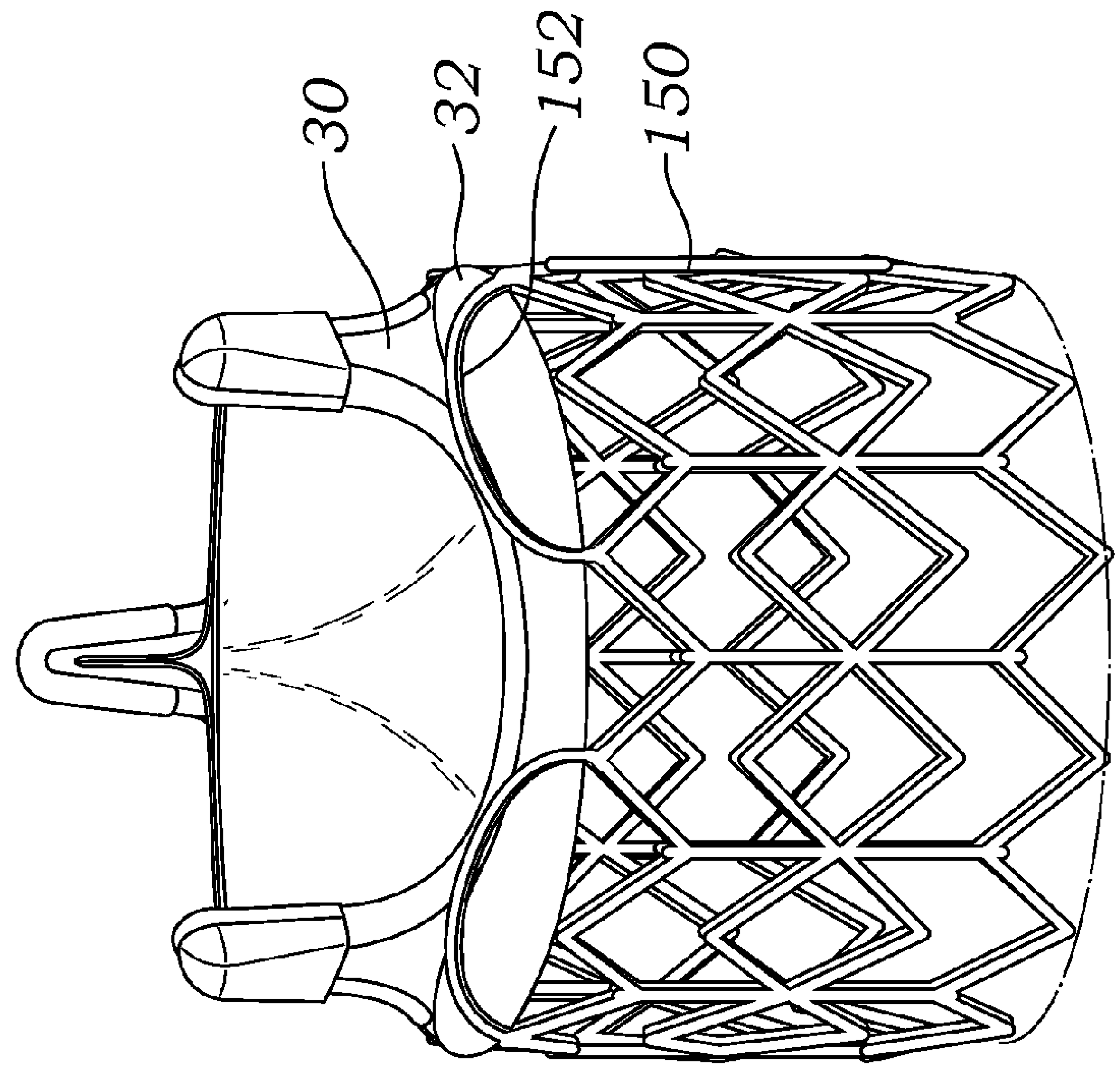


Fig. 15A

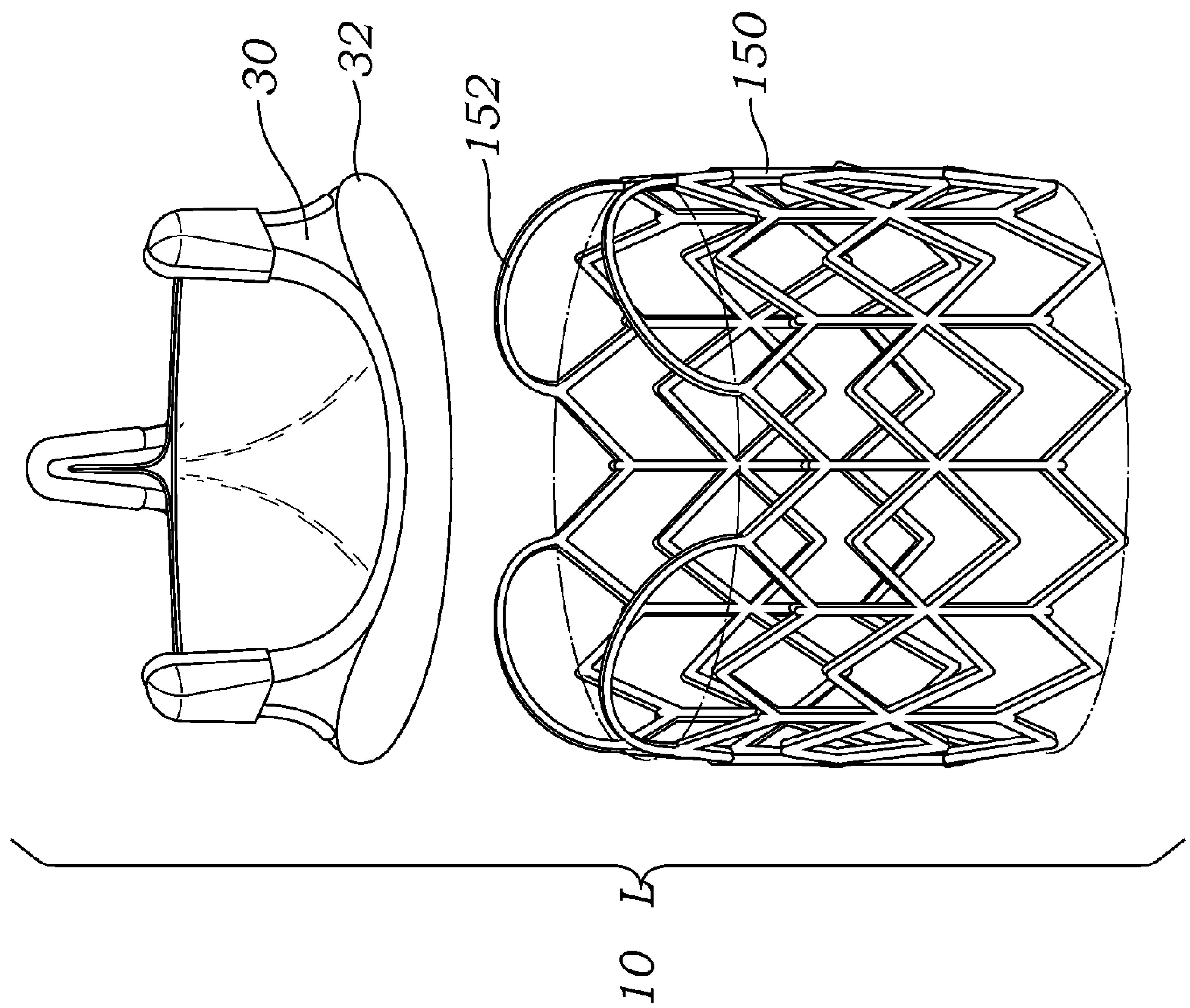


Fig. 16A

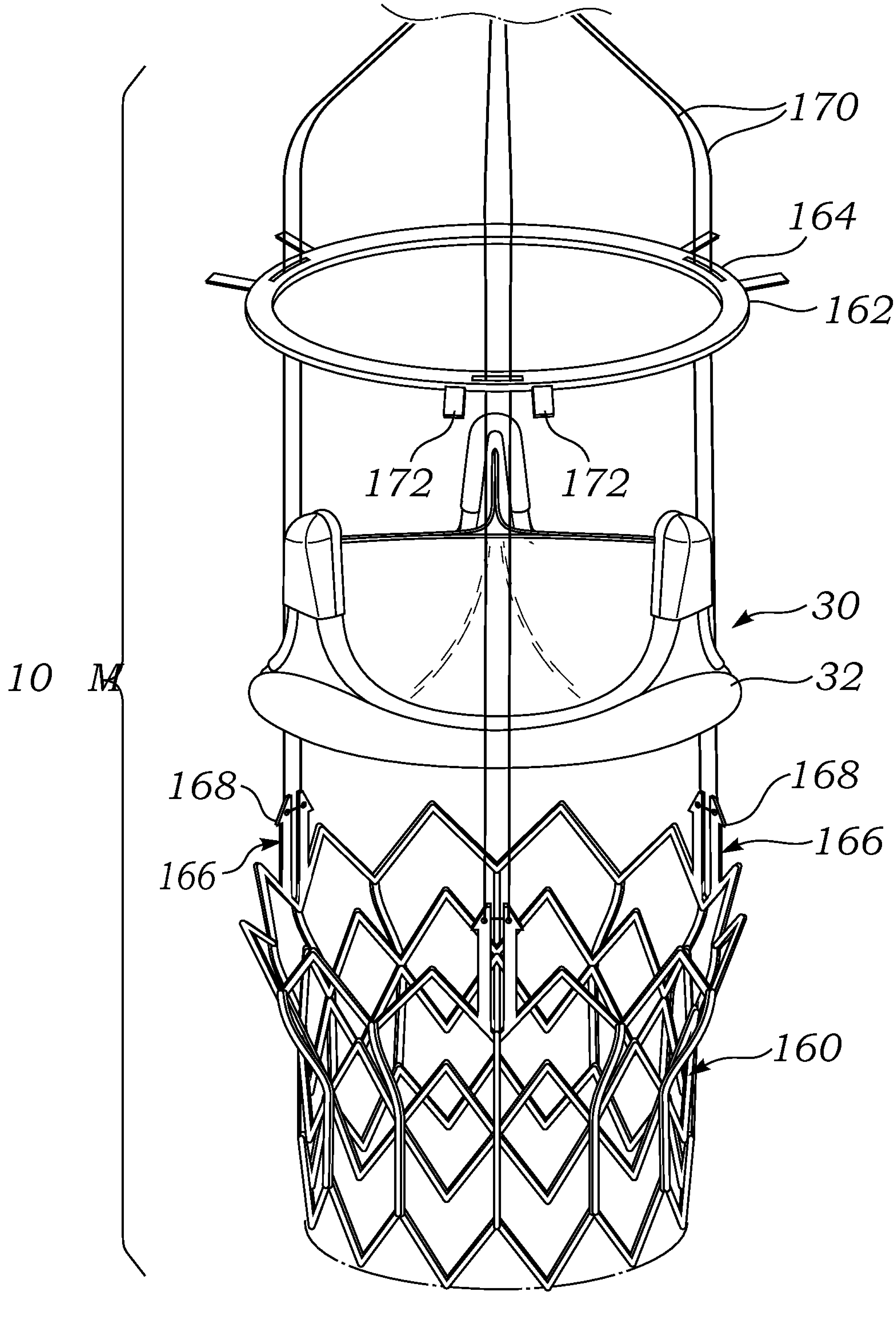


Fig. 16B

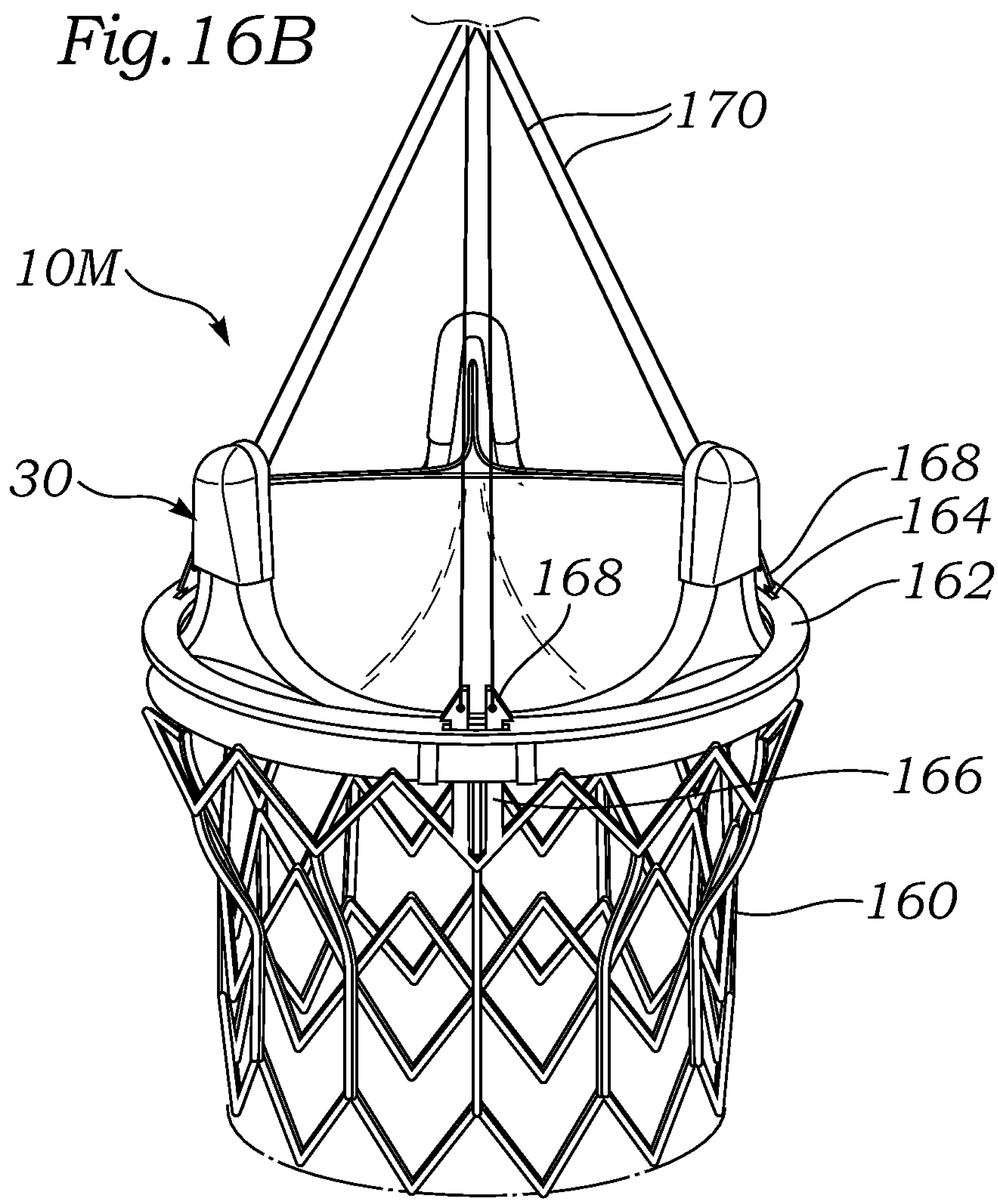


Fig. 17A

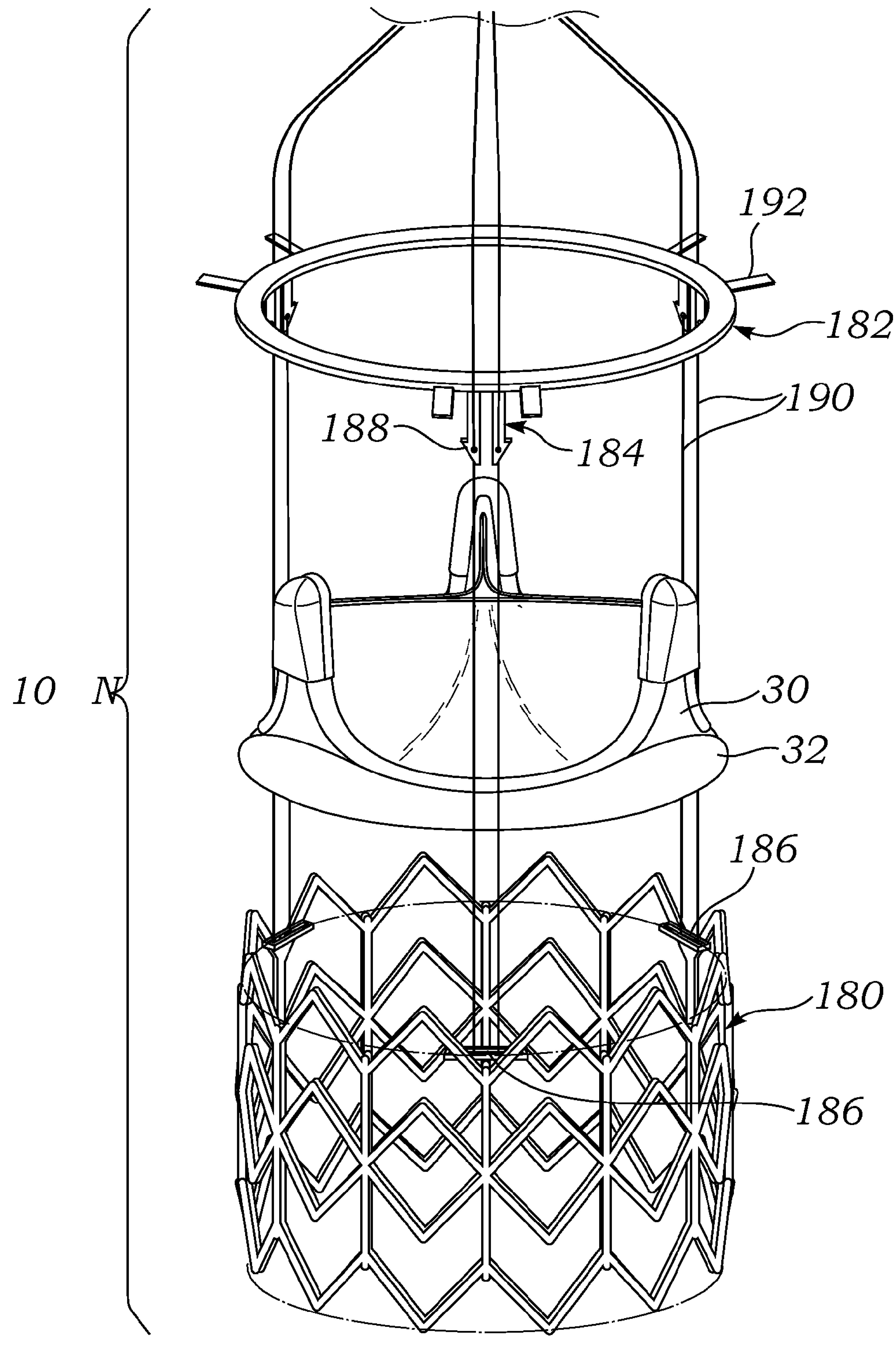


Fig. 17B

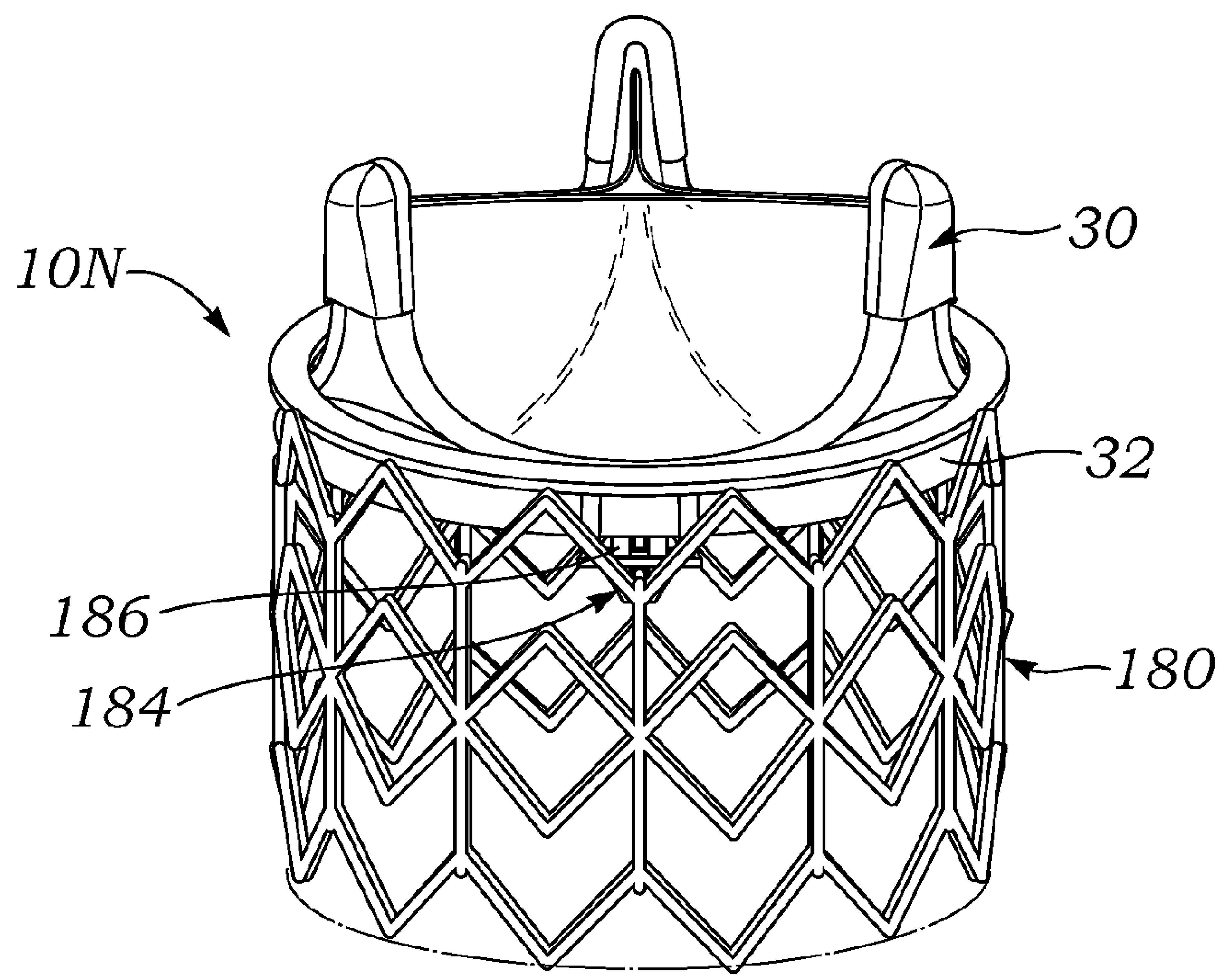


Fig. 18

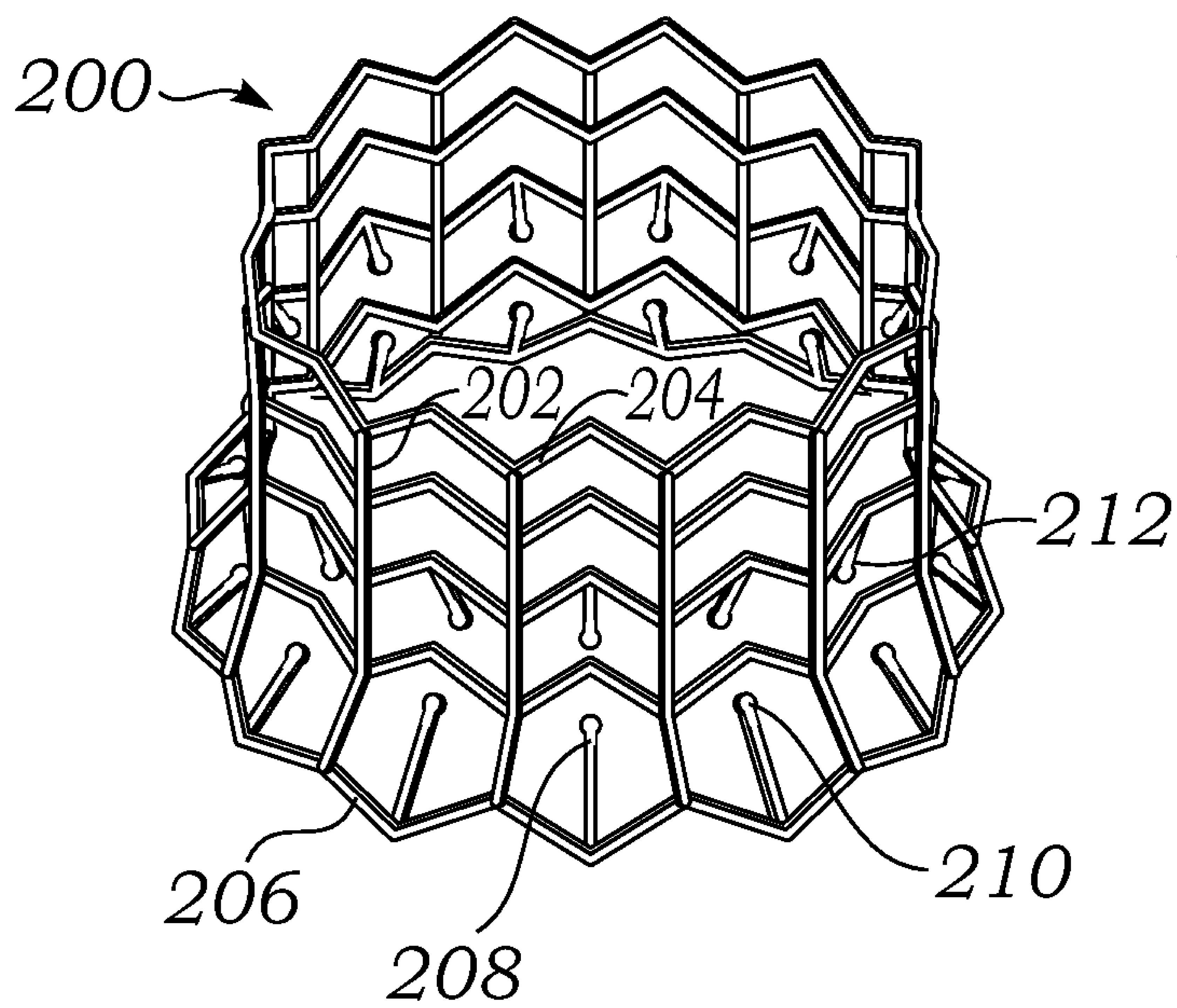


Fig. 19

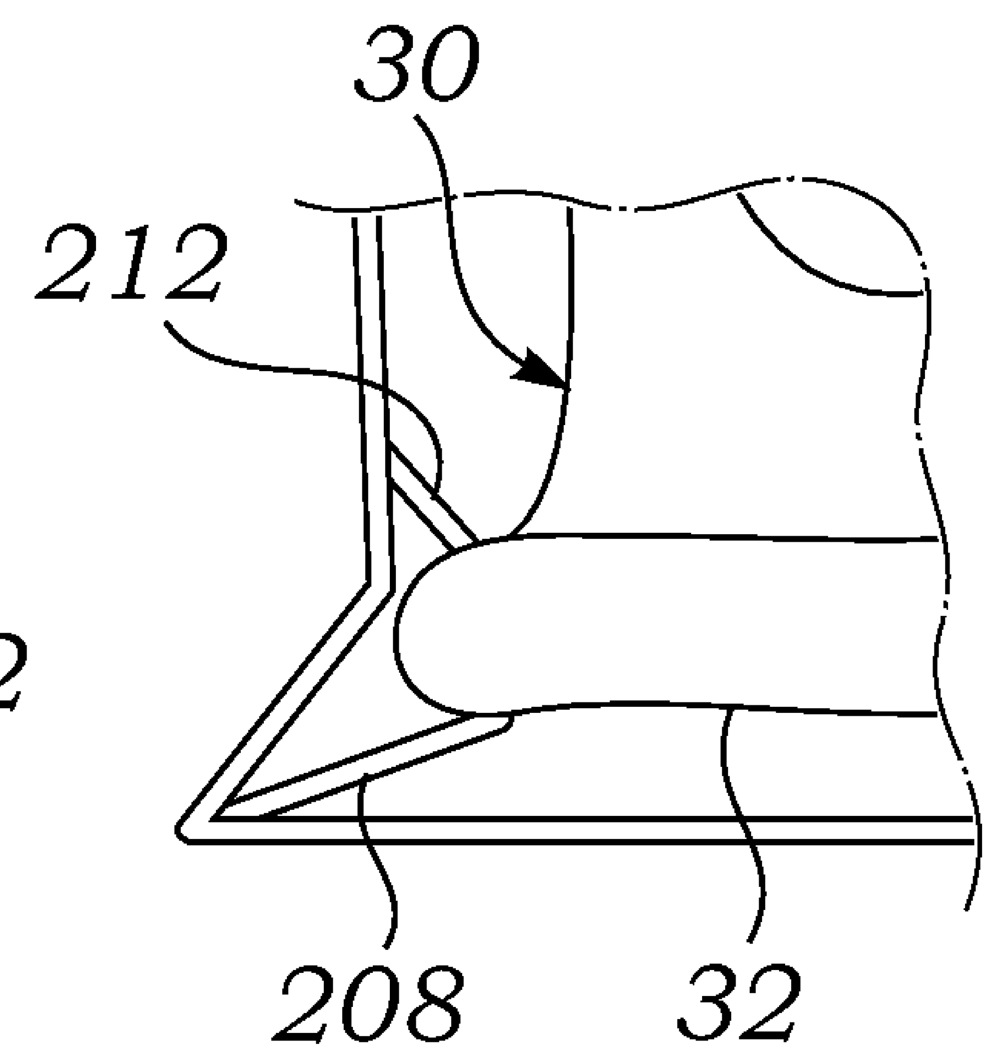


Fig. 20

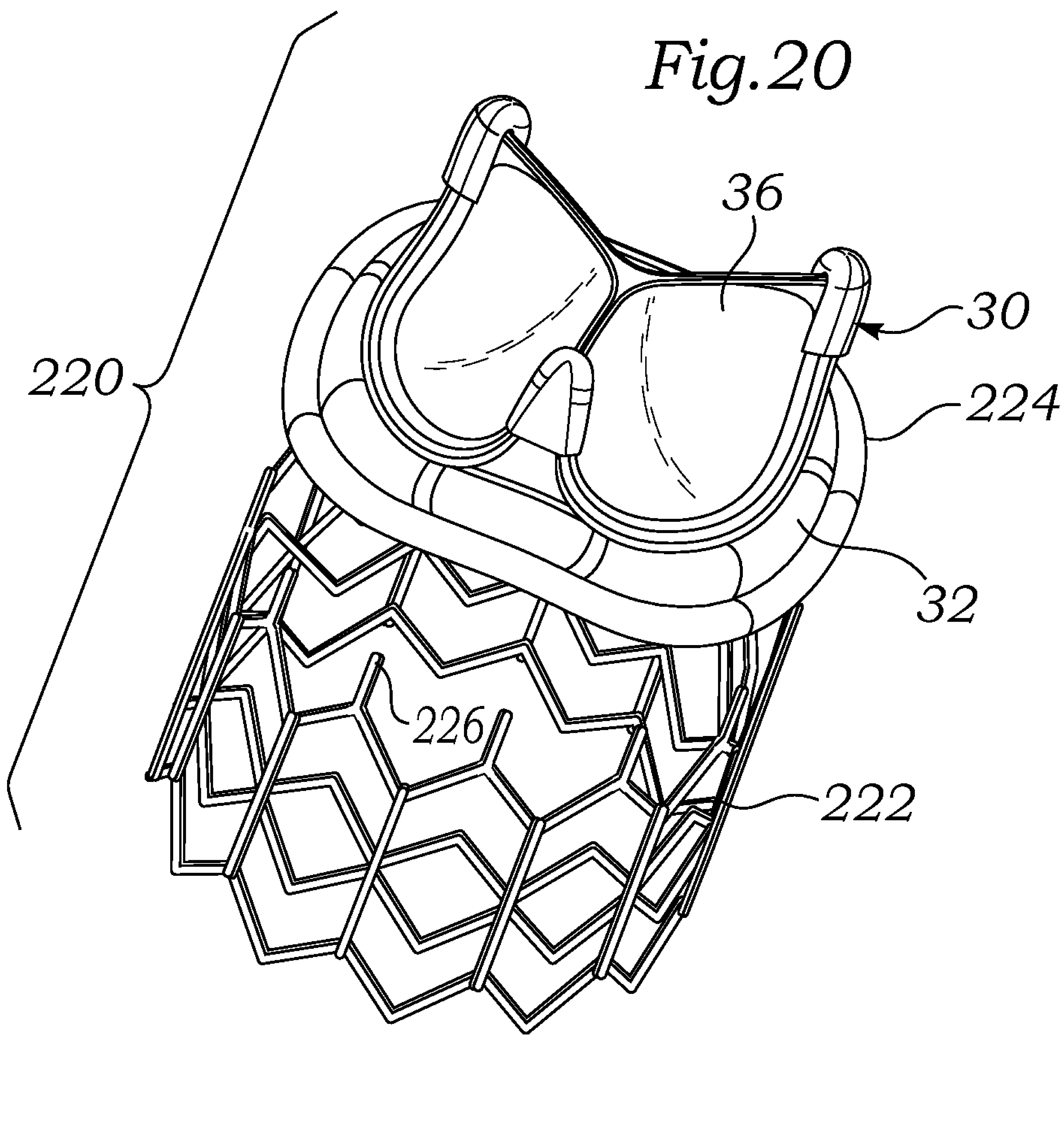


Fig. 21

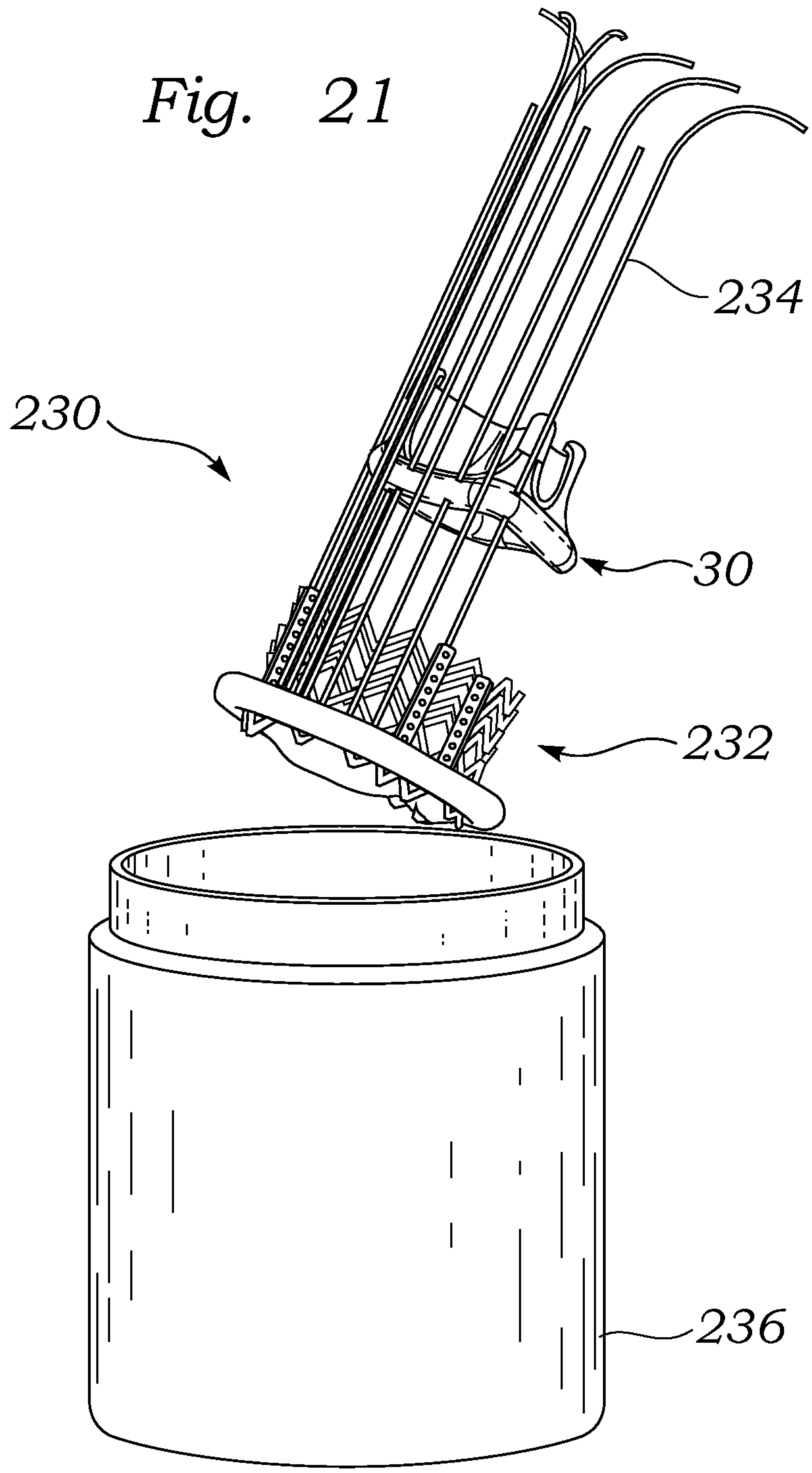


Fig. 22A

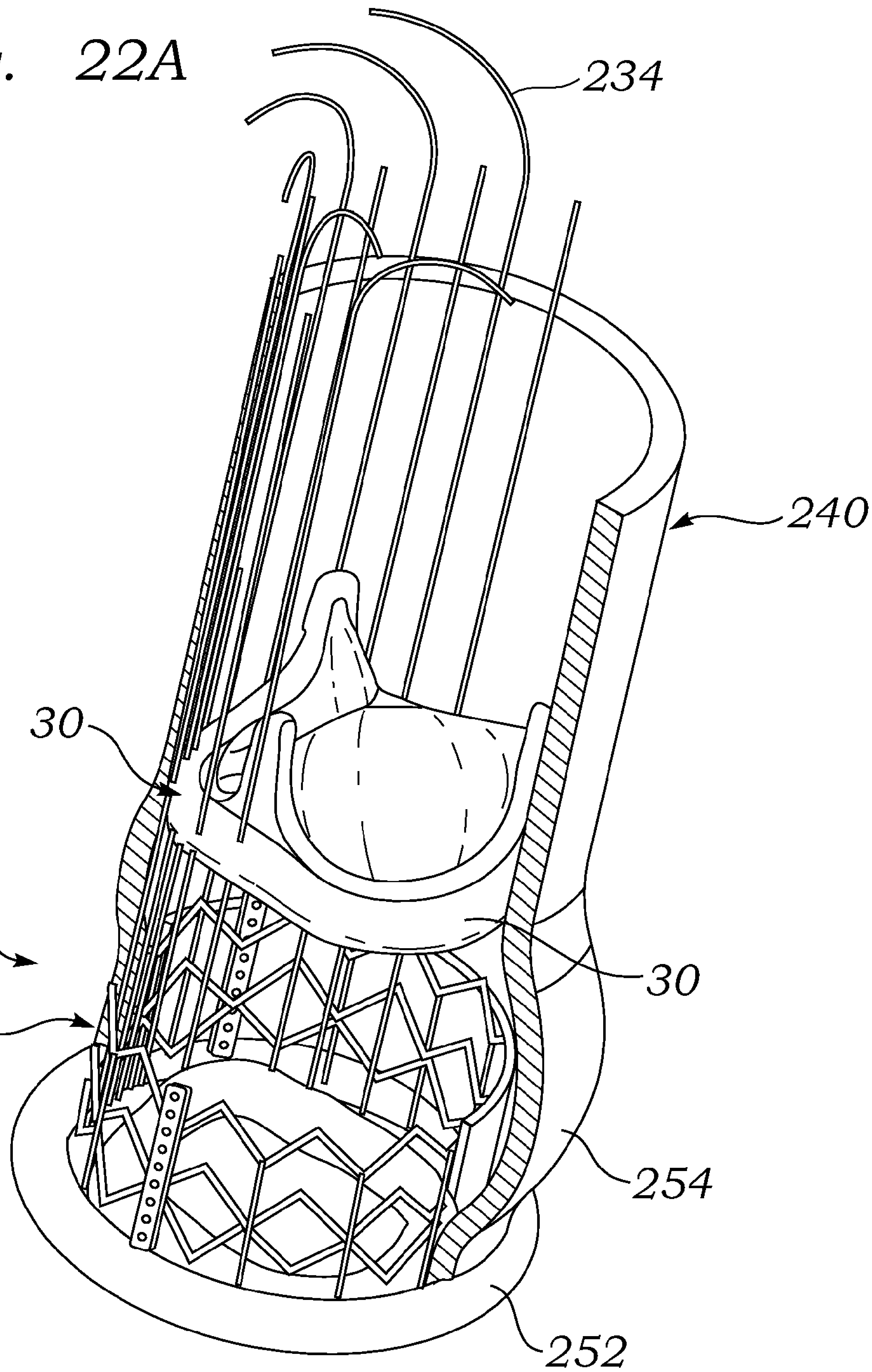


Fig. 22B

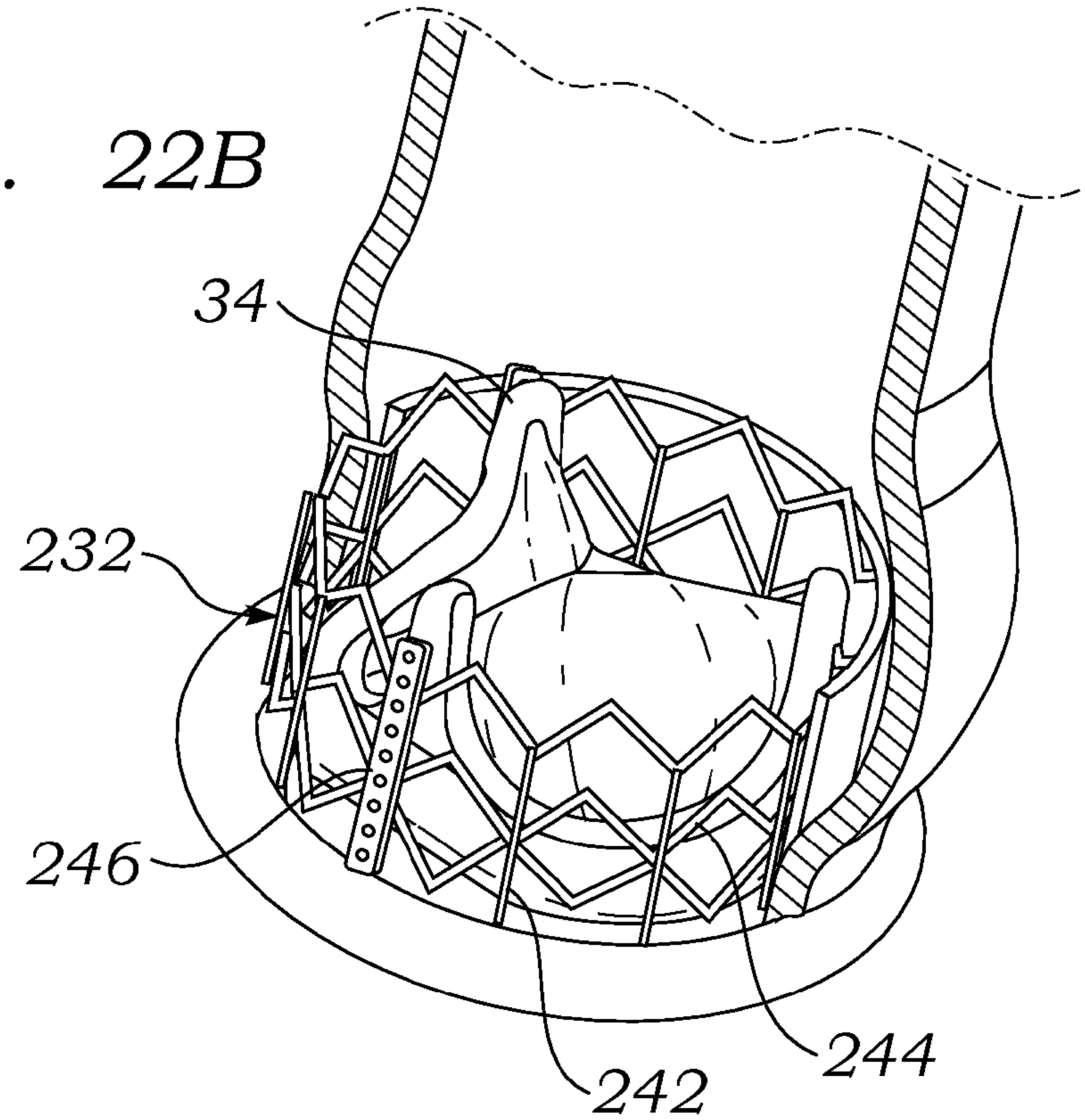
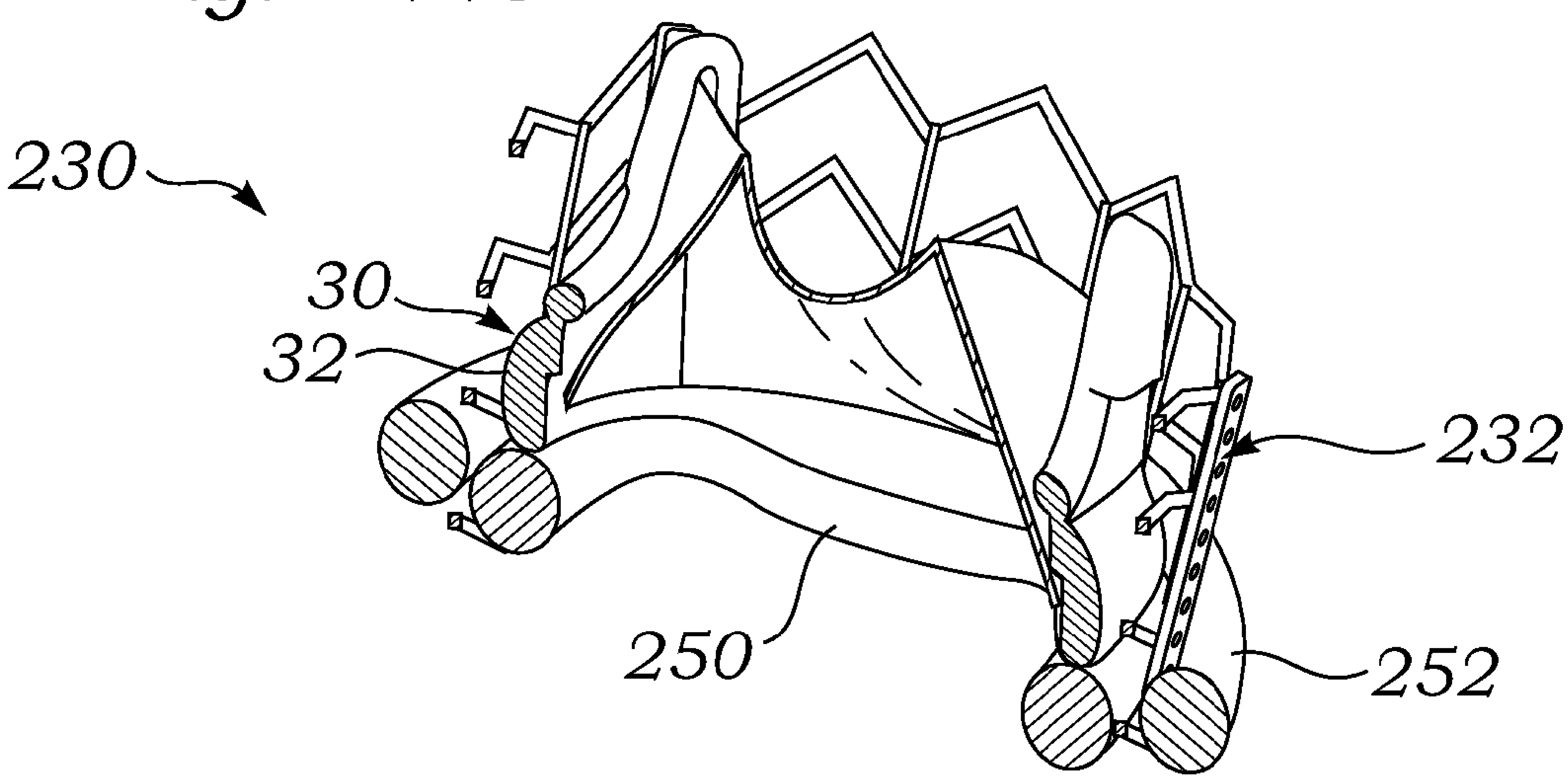


Fig. 22C



RAPID DEPLOYMENT PROSTHETIC HEART VALVE

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/954,822, filed Jul. 30, 2013, now U.S. Pat. No. 8,911,493, which is a continuation of U.S. patent application Ser. No. 11/441,406, filed May 24, 2006, now U.S. Pat. No. 8,500,798, which claims the benefit of U.S. Patent Application No. 60/684,443, filed on May 24, 2005, entitled "Prosthetic Valve for Implantation in a Body Channel", all the disclosures which are incorporated by reference herein in their entireties.

FIELD OF THE INVENTION

The present invention generally relates to prosthetic valves for implantation in body channels. More particularly, the present invention relates to prosthetic heart valves configured to be surgically implanted in less time than current valves.

BACKGROUND OF THE INVENTION

Due to aortic stenosis and other heart valve diseases, thousands of patients undergo surgery each year wherein the defective native heart valve is replaced by a prosthetic valve, either bioprosthetic or mechanical. When the valve is replaced, surgical implantation of the prosthetic valve typically requires an open-chest surgery during which the heart is stopped and patient placed on cardiopulmonary bypass (a so-called "heart-lung machine"). In one common surgical procedure, the diseased native valve leaflets are excised and a prosthetic valve is sutured to the surrounding tissue at the valve annulus. Because of the trauma associated with the procedure and the attendant duration of extracorporeal blood circulation, some patients do not survive the surgical procedure or die shortly thereafter. It is well known that the risk to the patient increases with the amount of time required on extracorporeal circulation. Due to these risks, a substantial number of patients with defective valves are deemed inoperable because their condition is too frail to withstand the procedure. By some estimates, about 30 to 50% of the subjects suffering from aortic stenosis who are older than 80 years cannot be operated on for aortic valve replacement.

Because of the drawbacks associated with conventional open-heart surgery, percutaneous and minimally-invasive surgical approaches are garnering intense attention. In one technique, a prosthetic valve is configured to be implanted in a much less invasive procedure by way of catheterization. For instance, U.S. Pat. No. 5,411,552 to Andersen et al. describes a collapsible valve percutaneously introduced in a compressed state through a catheter and expanded in the desired position by balloon inflation. Although these remote implantation techniques have shown great promise for treating certain patients, replacing a valve via surgical intervention is still the preferred treatment procedure. One hurdle to the acceptance of remote implantation is resistance from doctors who are understandably anxious about converting from an effective, if imperfect, regimen to a novel approach that promises great outcomes but is relatively foreign. In conjunction with the understandable caution exercised by surgeons in switching to new regimens of heart valve replacement, regulatory bodies around the world are moving slowly as well. Numerous successful clinical trials and follow-up studies are in process, but much more experience

with these new technologies will be required before they are completely accepted. One question that remains unanswered is whether the new expandable valves will have the same durability as conventional prosthetic heart valves.

Accordingly, there is a need for an improved device and associated method of use wherein a prosthetic valve can be surgically implanted in a body channel in a more efficient procedure that reduces the time required on extracorporeal circulation. It is desirable that such a device and method be capable of helping patients with defective valves that are deemed inoperable because their condition is too frail to withstand a lengthy conventional surgical procedure. The present invention addresses this need.

SUMMARY OF THE INVENTION

Various embodiments of the present invention provide prosthetic valves and methods of use for replacing a defective native valve in a human heart. Certain embodiments are particularly well adapted for use in a surgical procedure for quickly and easily replacing a heart valve while minimizing time using extracorporeal circulation (i.e., bypass pump).

In one embodiment, a method for treating a native aortic valve in a human heart, comprises: 1) accessing a native valve through an opening in a chest; 2) advancing an expandable support structure to the site of a native aortic valve, the support structure being radially compressed during the advancement; 3) radially expanding the support structure at the site of the native aortic valve; and 4) mechanically coupling a valve member to the expanded support structure, wherein the valve member replaces the function of the native aortic valve. A further understanding of the nature and advantages of the present invention are set forth in the following description and claims, particularly when considered in conjunction with the accompanying drawings in which like parts bear like reference numerals.

In one variation, the support structure is a stent, which may comprise a metallic frame. In one embodiment, at least a portion of the metallic frame is made of stainless steel. In another embodiment, at least a portion of the metallic frame is made of a shape memory material. The valve member may take a variety of forms. In one preferred embodiment, the valve member comprises biological tissue. The valve member further comprises a coupling portion configured to be connected to the support structure in a quick and efficient manner. In another variation of this method, the metallic frame is viewed under fluoroscopy during advancement of the prosthetic valve toward the native aortic valve.

The native valve leaflets may be removed before delivering the prosthetic valve. Alternatively, the native leaflets may be left in place to reduce surgery time and to provide a stable base for fixing the support structure within the native valve. In one advantage of this method, the native leaflets recoil inward to enhance the fixation of the metallic frame in the body channel. When the native leaflets are left in place, a balloon or other expansion member may be used to push the valve leaflets out of the way and thereby dilate the native valve before implantation of the support structure.

In another preferred embodiment, a method for treating a native aortic valve in a human heart, comprises accessing a native valve through an opening in a chest; advancing an expandable member to a position within the native aortic valve, the native aortic valve having at least two valvular leaflets; dilating the native aortic valve by expanding the expandable member to push aside the valvular leaflets of the native aortic valve; collapsing the expandable member and withdrawing the expandable member from the native aortic valve; advancing an expandable support structure to a position within the dilated native aortic valve, the support structure being radially compressed during the advancement; radially expanding the support structure within the dilated aortic valve, wherein the expanded support structure maintains the native aortic valve in the dilated condition; and coupling a valve member to the expanded support structure, wherein the valve member replaces the function of the native aortic valve.

In another aspect, an improved prosthetic valve comprises an expandable stent sized for implantation at the site of a native aortic valve, the stent having a coupling means (e.g., a plurality of tines extending from a first end thereof); and a valve member comprising three leaflets mounted on a base portion. The coupling means is configured for attachment to the valve member. Alternatively, the coupling means may be provided on the valve member or on both the stent and valve member.

A particularly useful configuration of the present invention is a two-stage prosthetic heart valve, comprising an expandable anchoring member sized to contact a heart valve annulus in an expanded state and a substantially non-expandable valve member configured for connection to the anchoring member. Desirably, the valve member includes a base ring surrounding an inflow end thereof, and the anchoring member comprises a tubular structure having connectors adapted to engage the base ring. The connectors may comprise prongs that change shape and engage the base ring. For example, the base ring may be made of a suture-permeable material, and the prongs are configured to pierce the base ring, or the prongs are shaped to wrap around the base ring.

In an exemplary embodiment, the valve member includes a plurality of discrete connectors spaced around a peripheral inflow end thereof, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof. The connectors on the valve member and anchoring member engage one another by displacing the valve member toward the anchoring member. For instance, the connectors on either the valve member or anchoring member comprise latches, and the connectors on the other of the valve member or anchoring member comprise brackets, the latches configured to engage and lock to the brackets upon axial movement of the latches and brackets toward one another. Additionally, a plurality of guide filaments may be provided, at least one for each of the connectors on the anchoring member and slidingly received by the associated connector on the valve member. The guide filaments guide the valve member in proper orientation with respect to the anchoring member to ensure engagement of the mating connectors.

Desirably, the anchoring member comprises a stent having a wider outflow end than an inflow end thereof, wherein the valve member comprises a base ring surrounding an inflow end thereof that fits within the outflow end of the stent. In one embodiment, the valve member includes a suture-permeable base ring surrounding an inflow end thereof, and the anchoring member comprises a tubular structure having a suture-permeable fixation ring attached thereto, wherein the valve member connects to the anchoring member via sutures looped between the base ring and the fixation ring.

Another embodiment of the present invention comprises a two-stage prosthetic heart valve, having an expandable anchoring member sized to contact a heart valve annulus in an expanded state, a valve member, and an adapter sized to surround the valve member and engage the anchoring member, to connect the valve member and anchoring member. The adapter may be an annular ring or a wireform-shaped member that closely surrounds and conforms to cusps and commissures of a flexible leaflet valve member.

Whatever its shape, the adapter desirably includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof. The connectors on the adapter and anchoring member are configured to engage one another by displacing the adapter toward the anchoring member. For example, the connectors on either the adapter or anchoring member comprise latches, and the connectors on the other of the adapter or anchoring member comprise brackets, the latches being configured to engage and lock to the brackets upon axial movement of the latches and brackets toward one another. In addition, the valve member preferably has a base ring surrounding an inflow end thereof, and the adapter further includes a plurality of connectors adapted to engage and couple the adapter directly to the base ring.

Another aspect of the present invention is a system for retrofitting a conventional prosthetic heart valve, comprising an off-the-shelf, non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through the sewing ring in an open-heart procedure. An expandable anchoring member contacts and anchors to a heart valve annulus in an expanded state. Coupling means connects the prosthetic heart valve to the anchoring member, the prosthetic heart valve thus being attached to the heart valve annulus via the anchoring member.

In the system for retrofitting a conventional prosthetic heart valve, the anchoring member may comprise a tubular structure having a suture-permeable fixation ring attached thereto, wherein the coupling means comprises sutures looped between the base ring and the fixation ring. An adapter sized to surround the heart valve engages the anchoring member, to connect the heart valve and anchoring member. The adapter may be annular or wireform-shaped. Desirably, the adapter includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof, the connectors on the adapter and anchoring member being configured to engage one another by displacing the adapter toward the anchoring member.

A surgical method of implanting a prosthetic heart valve of the present invention in a patient involves providing a two-stage prosthetic heart valve comprising an expandable anchoring member and a valve member, the anchoring member being sized to contact a heart valve annulus in an expanded state and the valve member being configured to connect to the anchoring member. The patient is prepared for surgery by placing him/her on cardiopulmonary bypass. The surgeon creates a direct access pathway to the heart valve annulus that preferably permits direct (i.e., naked eye) visualization of the heart valve annulus. The anchoring member is delivered and expanded to contact the valve annulus, and the valve member is delivered and connected to the anchoring member. Preferably, the direct access pathway is created by performing open-heart surgery. The method may include balloon-expanding the anchoring member. Further, the valve member may be expandable and the method includes delivering the valve member in a compressed state and expanding it prior to connecting it to the anchoring member.

In one embodiment, the valve member and the anchoring member are provided with mating connectors, and the step of delivering and connecting the valve member to the anchoring member comprises axially displacing the valve member toward the anchoring member so that the mating connectors engage. In another embodiment, the anchoring member comprises a stent having an outflow end larger than an inflow end thereof, and the valve member comprises a non-expandable valve member having a base ring on an inflow end thereof sized to fit within the outflow end of the stent. The anchoring member may be provided with bendable connectors on an outflow end thereof, and the method includes causing the connectors to bend inward and engage a peripheral base ring of the valve member. For example, a bending tool may be used to bend connectors inward.

Another surgical method of implanting a two-stage prosthetic heart valve in a patient of the present invention includes providing an expandable anchoring member sized to contact a heart valve annulus in an expanded state, delivering and attaching the anchoring member to the heart valve annulus, providing a non-expandable valve member, and delivering and connecting the valve member to the anchoring member. The valve member and the anchoring member may be provided with mating connectors, and the step of delivering and connecting the valve member to the anchoring member comprises axially displacing the valve member toward the anchoring member so that the mating connectors engage. Desirably, the anchoring member comprises a stent having an outflow end larger than an inflow end thereof, and wherein the valve member comprises a base ring on an inflow end thereof sized to fit within the outflow end of the stent. The anchoring member may be provided with bendable connectors on an outflow end thereof, and the method includes causing the connectors to bend inward and engage a peripheral base ring of the valve member, such as by using a bending tool.

In an exemplary embodiment, the valve member includes a base ring on an inflow end thereof, and the method further includes providing an adapter sized to surround the valve member and seat on the base ring. The method therefore includes the step of delivering and connecting the valve member and coupling the adapter to the anchoring member. For instance, the adapter includes a plurality of discrete connectors, and the anchoring member comprises a tubular structure having a plurality of mating connectors spaced around a peripheral outflow end thereof. The step of coupling the adapter to the anchoring member comprises displacing the adapter toward the anchoring member to engage the mating connectors thereon. Additionally, the adapter may further have a plurality of connectors adapted to engage and couple the adapter directly to the base ring, and the method includes causing the connectors to engage the base ring.

In a still further surgical method of implanting a prosthetic heart valve in a patient, a prosthetic heart valve and a separate expandable anchoring member are provided. The prosthetic heart valve and anchoring member are positioned within a valve dilator/delivery tube having an exterior diameter sized to dilate a heart valve annulus. The valve dilator/delivery tube advances to the heart valve annulus, and the annulus is dilated using the valve dilator/delivery tube. The anchoring member is expulsed from the tube and expanded to contact the heart valve annulus. The prosthetic heart valve is then expulsed from the valve dilator/delivery tube, and connected to the anchoring member.

Another method of the present invention comprises retrofitting and rapidly implanting a conventional prosthetic heart valve in a patient. The method includes providing an off-the-shelf non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through the sewing ring in an open-heart procedure. An expandable tissue anchoring member sized to contact a heart valve annulus in an expanded state is delivered and expanded into contact with the heart valve annulus. Finally, the prosthetic heart valve is delivered and connected to the tissue anchoring member.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be explained and other advantages and features will appear with reference to the accompanying schematical drawings wherein:

FIG. **1** is an exploded perspective view illustrating a preferred embodiment of a two-stage prosthetic valve comprising a stent portion and a valve member, wherein the valve member may be quickly and easily connected to the stent portion.

FIG. **2** illustrates the valve embodiment of FIG. **1** after the valve member has been attached to the stent portion by crimping portions of the stent over the commissural points of the valve member.

FIG. **3** is an exploded perspective view of an alternative embodiment wherein the stent is provided with a plurality of tines configured to be crimped to a ring along the base of the valve member.

FIG. **4** illustrates the valve embodiment of FIG. **3** after the valve member has been attached to the stent portion by crimping the tines on to the valve member.

FIG. **4**A is a sectional view through one side of the prosthetic heart valve of FIG. **4** taken along line **4**A-**4**A and showing one configuration of tines connecting through a sewing ring portion of the valve member.

FIG. **5** is an exploded perspective view of an alternative embodiment wherein slotted posts are provided on the stent for coupling to protruding members on the valve member.

FIG. **5**A is an enlarged view of one of the slotted posts provided on the stent of FIG. **5**.

FIGS. **6** and **6**A illustrate another alternative embodiment similar to FIGS. **5** and **5**A wherein the posts are configured with L-shaped slots for locking the valve member to the stent.

FIG. **7** is a sectional view through a body channel that illustrates an alternative embodiment of prosthetic heart valves wherein first and second stents are provided for anchoring a valve member within the body channel.

FIG. **8** is an exploded perspective view of an alternative embodiment wherein the stent has a small diameter and a large diameter and wherein an expandable valve member is deployed within the large diameter.

FIG. **9**A is an exploded perspective view of another alternative embodiment of a two part prosthetic valve wherein a ring portion along the base of the valve member snaps into a groove formed in the stent.

FIG. **9**B illustrates the embodiment of FIG. **9**A with the valve member connected to the stent.

FIG. **10** is an exploded perspective view of another alternative embodiment wherein the valve member and the stent are provided with corresponding threaded portions for threadably engaging the valve member to the stent.

FIG. **11** is an exploded perspective view of an alternative prosthetic heart valve of the present invention having a valve member, stent, and a threaded locking ring for coupling the two together.

FIGS. **12**A and **12**B are exploded and assembled perspective views of an alternative two-stage prosthetic heart valve having a valve member and tubular, expandable stent with tabs on an outflow end for coupling to the valve member.

FIGS. **12**C and **12**D are sectional views through one side of the prosthetic heart valve of FIG. **12**B schematically illustrating an exemplary tool that may be used to bend the tabs on the outflow end of the stent around a sewing ring of the valve member.

FIGS. **13**A and **13**B are exploded and assembled perspective views of an alternative prosthetic heart valve of the present invention wherein a valve member and stent with tabs are coupled together in conjunction with a locking ring.

FIGS. **14**A and **14**B are exploded and assembled perspective views of a still further prosthetic heart valve wherein a valve member and tubular, expandable stent are coupled together using a wireform-shaped adapter having tabs.

FIGS. **15**A and **15**B are exploded and assembled perspective views of a prosthetic heart valve having a valve member and stent with locking bands on an outflow end.

FIGS. **16**A and **16**B are exploded and assembled perspective views of an alternative prosthetic heart valve wherein a stent exhibits locking clips on an outflow end that are guided through mating slits on a locking ring to join the stent to a valve member.

FIGS. **17**A and **17**B are exploded and assembled perspective views of an alternative prosthetic heart valve wherein a stent has brackets on an outflow end that receive guided locking clips on a locking ring to join the stent to a valve member.

FIG. **18** is a perspective view of an alternative stent for use in a prosthetic heart valve of the present invention.

FIG. **19** is a detailed sectional view through an inflow side of a prosthetic heart valve utilizing the stent of FIG. **18** and showing a valve member base ring captured between two sets of prongs.

FIG. **20** is a perspective exploded view of a prosthetic heart valve having a tubular stent with upstanding tines and a valve member with an additional adapter ring arranged around a base ring.

FIG. **21** is an exploded perspective view of an exemplary prosthetic heart valve having an expandable stent and non-expandable valve member connected by an array of parachute sutures being removed from a storage jar.

FIGS. **22**A-**22**C are several views of the implantation of the prosthetic heart valve of FIG. **21** assisted by a tubular valve dilator/delivery tube.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention attempts to overcome drawbacks associated with conventional, open-heart surgery, while also adopting some of the techniques of newer technologies which decrease the duration of the treatment procedure. The prosthetic heart valves of the present invention are primarily intended to be delivered and implanted using conventional surgical techniques, including the aforementioned open-heart surgery. There are a number of approaches in such surgeries, all of which result in the formation of a direct access pathway to the particular heart valve annulus. For clarification, a direct access pathway is one that permits direct (i.e., naked eye) visualization of the heart valve annulus. In addition, it will be recognized that embodiments of the two-stage prosthetic heart valves described herein may also be configured for delivery using percutaneous approaches, and those minimally-invasive surgical approaches that require remote implantation of the valve using indirect visualization.

One primary aspect of the present invention is a two-stage prosthetic heart valve wherein the tasks of implanting a tissue anchor and a valve member are somewhat separated and certain advantages result. For example, a two-stage prosthetic heart valve of the present invention may have an expandable tissue anchoring member that is secured in the appropriate location using a balloon or other expansion technique. A valve member is then coupled to the tissue anchoring member in a separate or sequential operation. By utilizing an expandable anchoring member, the duration of the initial anchoring operation is greatly reduced as compared with a conventional sewing procedure utilizing an array of sutures. The expandable anchoring member may simply be radially expanded outward into contact with the implantation site, or may be provided with additional anchoring means, such as barbs. The operation may be carried out using a conventional open-heart approach and cardiopulmonary bypass. In one advantageous feature, the time on bypass is greatly reduced due to the relative speed of implanting the expandable anchoring member.

For definitional purposes, the term "tissue anchoring member," or simply "anchoring member" refers to a structural component of a heart valve that is capable of attaching to tissue of a heart valve annulus. The anchoring members described herein are most typically tubular stents, or stents having varying diameters. A stent is normally formed of a biocompatible metal wire frame, such as stainless steel or Nitinol. Other anchoring members that could be used with valves of the present invention include rigid rings, spirally-wound tubes, and other such tubes that fit tightly within a valve annulus and define an orifice therethrough for the passage of blood, or within which a valve member is mounted. It is entirely conceivable, however, that the anchoring member could be separate clamps or hooks that do not define a continuous periphery. Although such devices sacrifice some dynamic stability, these devices can be configured to work well in conjunction with a particular valve member.

The term "valve member" refers to that component of a heart valve that possesses the fluid occluding surfaces to prevent blood flow in one direction while permitting it in another. As mentioned above, various constructions of valve numbers are available, including those with flexible leaflets and those with rigid leaflets or a ball and cage arrangement. The leaflets may be bioprosthetic, synthetic, or metallic.

A primary focus of the present invention is the two-stage prosthetic heart valve having a first stage in which an anchoring member secures to a valve annulus, and a subsequent second stage in which a valve member connects to the anchoring member. It should be noted that these stages can be done almost simultaneously, such as if the two components were mounted on the same delivery device, or can be done in two separate clinical steps, with the anchoring member deployed using a first delivery device, and then the valve member using another delivery device. It should also be noted that the term "two-stage" does not necessarily limit the valve to just two parts, as will be seen below.

Another potential benefit of a two-stage prosthetic heart valve, including an anchoring member and a valve member, is that the valve member may be replaced after implantation without replacing the anchoring member. That is, an easily detachable means for coupling the valve member and anchoring member may be used that permits a new valve member to be implanted with relative ease. Various configurations for coupling the valve member and anchoring member are described herein.

It should be understood, therefore, that certain benefits of the invention are independent of whether the anchoring member or valve member are expandable or not. That is, various embodiments illustrate an expandable anchoring member coupled to a conventional valve member. However, the same coupling structure may be utilized for a non-expandable anchoring member and conventional valve member. Additionally, although a primary embodiment of the present invention is an expandable anchoring member coupled with a conventional valve member, both could be expandable and introduced percutaneously or through a minimally-invasive approach. Therefore, the invention should not be construed as being limited in these regards, but instead should be interpreted via the appended claims.

As a point of further definition, the term "expandable" is used herein to refer to a component of the heart valve capable of expanding from a first, delivery diameter to a second, implantation diameter. An expandable structure, therefore, does not mean one that might undergo slight expansion from a rise in temperature, or other such incidental cause. Conversely, "non-expandable" should not be interpreted to mean completely rigid or a dimensionally stable, as some slight expansion of conventional "non-expandable" heart valves, for example, may be observed.

In the description that follows, the term "body channel" is used to define a blood conduit or vessel within the body. Of course, the particular application of the prosthetic heart valve determines the body channel at issue. An aortic valve replacement, for example, would be implanted in, or adjacent to, the aortic annulus. Likewise, a mitral valve replacement will be implanted at the mitral annulus. Certain features of the present invention are particularly advantageous for one implantation site or the other. However, unless the combination is structurally impossible, or excluded by claim language, any of the heart valve embodiments described herein could be implanted in any body channel.

With reference now to FIG. **1**, one preferred embodiment of an improved prosthetic valve **10** generally includes an expandable anchoring member or stent **20** and a valve member **30**. The stent provides a support structure for anchoring the valve member within a body lumen. Although a stent is described for purposes of illustration, any support structure capable of anchoring the valve member to the body lumen may be used. As will be described in more detail below, the prosthetic valve is configured such that the valve member may be quickly and easily connected to the stent. It should be noted here, that the anchoring members or stents described herein can be a variety of designs, including having the diamond-shaped openings shown or other configurations detailed below. The material depends on the mode of delivery (i.e., balloon- or self-expanding), and the stent can be bare strut material or covered to promote in-growth and/or to reduce paravalvular leakage. For example, a suitable cover that is often used is a sleeve of fabric such as Dacron.

The stent may be securely deployed in the body channel using an expandable member, such as, for example, a balloon. Because the stent is expanded before the valve member is attached, the valve member will not be damaged or otherwise adversely affected during the stent deployment. After the stent has been deployed in the body channel, the valve member may be connected to the stent. In one preferred application, the two-stage prosthetic valve is well-suited for use in heart valve replacement. In this application, the stent may be advantageously used to push the native leaflets aside such that the valve member can replace the function of the native valve. The anchoring members or stents described herein could include barbs or other such tissue anchors to further secure the stent to the tissue. In one preferred embodiment, the barbs are deployable (e.g., configured to extend or be pushed radially outward) by the expansion of a balloon.

In another advantageous feature, the two-stage prosthetic valve illustrated in FIG. **1** provides a device and method for substantially reducing the time of the surgical procedure. This reduces the time required on extracorporeal circulation and thereby substantially reduces the risk to the patient. The surgical time is reduced because the stent may be deployed quickly and the valve member may be attached to the stent quickly. This simplifies and reduces the surgical time as compared with replacement valves that are sutured to the tissue after removing the native leaflets.

When used for aortic valve replacement, the valve member **30** preferably has three leaflets **36** which provide the valvular function for replacing the function of the native valve. In various preferred embodiments, the valve leaflets may be taken from another human heart (cadaver), a cow (bovine), a pig (porcine valve) or a horse (equine). In other preferred variations, the valve member may comprise mechanical components rather than biological tissue. In one preferred embodiment, the valve is compressible in diameter. Accordingly, the valve may be reduced in diameter for delivery into the stent and then expanded. The three leaflets are supported by three commissural posts **34**. A ring **32** is provided along the base portion of the valve member.

With continued reference to FIG. **1**, the stent **20** is provided with two diameters. A lower portion **22** has a small diameter and an upper portion **24** has a large diameter. The lower portion **22** is preferably sized to be deployed at the location of the native valve (e.g., along the aortic annulus). The upper portion **24** expands outwardly into the perspective cavity adjacent the native valve. For example, in an aortic valve replacement, the upper portion **24** expands into the area of the sinus cavities just downstream from the aortic annulus. Of course, care should be taken to orient the stent **20** so as not to block the coronary openings. The stent body is preferably configured with sufficient radial strength for pushing aside the native leaflets and holding the native leaflets open in a dilated condition. The native leaflets provide a stable base for holding the stent, thereby helping to securely anchor the stent in the body. To further secure the stent to the surrounding tissue, the lower portion may be configured with anchoring members, such as, for example, hooks or barbs (not shown).

The upper portion **24** of the stent **20** has a larger diameter sized for receiving the valve member **30**. A transition region **28** between the upper and lower portions of the stent body may be advantageously used to provide a seat for the bottom end of the valve member. The stent may further comprise a ridge (not shown) along an inner wall for providing a more definite seat portion within the stent.

With continued reference to FIG. **1**, the prosthetic valve **10** is provided with a coupling mechanism for securing the valve member **30** to the stent **20**. The coupling mechanism may take a variety of different forms. However, in the illustrated embodiment, the stent body comprises three posts **26** which correspond to the three commissural points **34** on the valve member. The three posts **26** are preferably formed of a malleable material such that the posts **26** may be crimped over the commissural points on the valve member. A bending tool (not shown) may be provided for crimping the posts **26** over the commissures of the valve member, or the posts **26** may be hinged or made of the shape memory material so as to curl once implanted in the body. With reference to FIG. **2**, the prosthetic valve **10** is illustrated in the assembled condition with the posts **26** crimped over the commissural points **34** of the valve member. In one variation, the three posts on the stent are formed with a recess for receiving the commissural points, such as in a snap-fit relationship.

In a preferred embodiment, the stent **20** is expandable, but the valve member **30** is a conventional, non-expandable prosthetic heart valve, such as the Carpentier-Edwards PERIMOUNT Magna® Aortic Heart Valve available from Edwards Lifesciences of Irvine, Calif. In this sense, a "conventional" prosthetic heart valve is an off-the-shelf (i.e., suitable for stand-alone sale and use) non-expandable prosthetic heart valve having a sewing ring capable of being implanted using sutures through the sewing ring in an open-heart procedure. An implant procedure therefore involves first delivering and expanding the stent **20** and the aortic annulus, and then coupling the valve member **30** thereto. Because the valve member **30** is non-expandable, the entire procedure is typically done using the conventional open-heart technique. However, because the stent **20** is delivered and implanted by simple expansion, the entire operation takes less time. This hybrid approach will also be much more comfortable to surgeons familiar with the open-heart procedures and conventional heart valves. Moreover, the relatively small change in procedure coupled with the use of proven heart valves should create a much easier regulatory path than strictly expandable, remote procedures.

A variation of the embodiment described in FIGS. **1** and **2** may incorporate an expandable stent **20** and an expandable valve member **30**. Although not shown, the valve member **30** may be capable of expansion within the body, such as the Cribier-Edwards Aortic Percutaneous Heart Valve, also available from Edwards Lifesciences. Therefore, the valve **10** may be implanted without an open-heart procedure, and even without stopping heart. In such a remote procedure, the three posts **26** on the stent **20** may be made of a shape memory material having a temperature-induced shape change once implanted. Alternatively, a tool for bending the posts **26** may be delivered along with the valve **10** and utilized when the valve member **30** seats within the stent **20**.

With reference now to FIG. **3**, an alternative prosthetic valve **10**A comprises a stent **40** provided with a bottom portion **42** and an upper flared portion **44**. A plurality of prongs or tines **46** is disposed along a top end of the flared portion **44**. The tines **46** are preferably bendable members configured to engage the ring portion **32** along the base of the valve member **30**. In one preferred embodiment, the tines **46** are crimped over the ring as shown in FIG. **4**. If desired, the tines **46** may have pointed tips for passing through a fabric or other similar material along the ring portion of the valve member, such as seen in FIG. **4**A.

Once again, the stent **40** is desirably an expandable member that can be easily delivered and implanted at the body channel. The valve member **30** may be conventional, or may also be expandable. The illustrated embodiment shows a conventional valve **30** having the sewing ring portion **32** surrounding an inflow end. Sewing rings are typically made of suture-permeable material covered with cloth. The tines **46** may be sharp enough to pierce the material of the sewing ring portion **32** (FIG. **4**A). In this regard, a conventional valve member **30** may be utilized without modification. In the alternative, the sewing ring portion **30** may be replaced with a more rigid peripheral band or ring, and the tines **46** are simply bent inward so as to fold over the ring and capture the valve member **31** on the top of the stent **40**. Desirably, a seat or rim of some sort is provided within the interior of the stent **40** so that the valve member **30** can easily be positioned therein. The tines **46** may be mechanically bent using a deployment tool (not shown), or they may be hinged or made of a shape memory material so as to curl inward upon reaching a certain temperature.

With reference now to FIG. **5**, another alternative prosthetic valve **10**B comprises an anchoring member or stent **50** provided with a cylindrical portion **52** and three posts **54** extending upward from the cylindrical portion. Each post **54** may be slotted, as illustrated in the enlarged view of FIG. **5**B, or formed with an orifice. Radially protruding members **38** are provided along the ring portion **32** of the valve member **30** for mating with the posts on the stent. The exemplary slot has a thin neck portion **58** wherein engagement members, such as angled teeth, are provided. The teeth are angled such that the slot widens as the protruding member **38** is pushed downward into the slot. After passing through the teeth into the capture portion **59**, the protruding member **38** is securely captured. Because the teeth are angled in only one direction, an upward force will not cause the slot to widen, thereby capturing the protruding member.

With reference now to FIG. **6**, yet another alternative embodiment of a component prosthetic valve **10**C is illustrated. The embodiment of FIG. **6** is similar to the embodiment illustrated and described above with respect to FIG. **5**. However, in this variation, the posts or connecting members **55** are provided with L-shaped slots **57** for receiving the protruding member disposed along the valve member. With reference to FIG. **6**A, an enlarged view of one preferred connecting member **55** is shown. The slot **57** of the connecting member **55** is shaped such that the protruding member **38** moves longitudinally into the slot and then rotationally to enter the capture portion. One or more teeth **58** may be provided for holding the protruding member in the capture portion. Alternatively, the protruding member **38** may be held in the slot **57** using friction or a mechanical locking member. In another alternative, a key lock system or "bayonet" attachment mechanism may be provided for coupling the valve member to the stent.

With reference now to FIG. **7**, another alternative prosthetic valve **10**D is illustrated wherein the valve member **30** is captured and held between first and second stents **60**, **62**. In use, the first stent **60** is expanded within a body channel such that the outer surface of the stent is in contact with the vessel wall **64**. The valve member **30** is then advanced through the body channel and into contact with the first stent. A ring **32** is preferably provided along the base portion of the valve member for contacting the outflow end of the first stent. The second stent is then advanced through the body channel and is deployed such that an inflow end of the second stent contacts a top surface of the ring **32** of the valve member for anchoring the valve member between the first and second stents.

The embodiment of FIG. **7** employs a slightly different means for connecting the valve member **30** the anchoring member. Primarily, stents **60**, **62** capture the ring **32** of the valve member **30** therebetween simply by providing upper and lower barriers to movement. The valve member **30** is desirably a non-expandable type, therefore the ring **32** is not overly susceptible to compression. By providing sufficient of the thickness of the stents **60**, **62**, the valve member **30** remains sandwiched therebetween. In this regard, the outflow end of the first stent **60** and the inflow end of the upper stent **62** are preferably flat or blunt so as not to dig into the ring **32**. Because of the anchoring function of the stents **60**, **62**, there is no need to suture the valve member **30**, and thus the ring **32** may be made relatively firm or rigid. Alternatively, the facing edges of the stents **60**, **62** may be provided with barbs or other such piercing devices, and the ring **32** provided as a conventional suture-permeable sewing ring.

As noted above, the anchoring members or stents described herein could include barbs or other anchors to further secure the stent to the tissue. Further, the barbs could be deployable (e.g., configured to extend or be pushed radially outward) by the expansion of a balloon. Likewise, the stent can be covered to promote in-growth and/or to reduce paravalvular leakage. The cover would be similar to those on other valves, e.g., a Dacron tube or the like.

Alternatively, the valve member may be constructed with a tubular frame or cage for engaging one or both stents **60**, **62**. In various preferred embodiments, the stents may be self-expanding or balloon-expandable. In one advantageous feature, the valve member **30** of this embodiment is not required to be mounted within a cylindrical frame or stent. Accordingly, the flow through area of the valve member may be maximized to improve valve function. In another variation, the first and second stents may be integrated as a single unit forming a chamber therebetween. In this variation, the valve member may be expanded within the chamber for securely deploying the valve member in the body channel.

With reference now to FIG. **8**, another alternative embodiment of a two-stage prosthetic valve **10**E is illustrated wherein the anchoring member or stent **70** is provided with a varying diameter. More particularly, a lower portion **72** of the stent has a small diameter sized for implantation at a native valve annulus. In one preferred configuration, the small diameter is about 23 mm. The stent also has an upper portion **74** with a larger diameter for receiving an expandable valve member **30**A. In one preferred configuration, the larger diameter is about 29 mm. In this embodiment, the valve member **30**A is provided as a tubular body that is radially expandable. The valve leaflets are disposed along the interior of the valve member.

The stent **70** preferably includes a circular ridge **76** formed along the transition region between the large and small diameters. The ridge provides a seat for the base of the valve member **30**A. In one preferred embodiment, the ridge **76** incorporates a support wire **78** that extends at least partially through the ridge for strength and may be used to provide a radiopaque marker. The remaining portion of the ridge may be formed of Dacron or any other suitable material. The stent **70** may be comprised of a screen or mesh. A cover **75**, such as a polymer sheet, may be provided along at least a portion of the stent to help prevent leakage and enhance sealing. In addition, a sponge or cloth may be provided along the exterior portion of the stent for further enhancing sealing.

The stent **70** of FIG. **8** may be self-expanding or balloon-expandable. When provided as a balloon-expandable stent, a expandable tapered (i.e., two diameter) balloon may be provided for deploying the stent. When configured for use with a stent having diameters of 23 mm and 29 mm, the balloon may have diameters of 22 mm and 28 mm, respectively.

With reference now to FIGS. **9**A and **9**B, another alternative embodiment of a component prosthetic valve **10**F is provided wherein a valve member **30** is configured for connection with an anchoring member or stent **90**. In this embodiment, the stent **90** is provided with a groove **94** formed in an inwardly-directed circumferential member **92**. The groove extends at least partially around the inner portion of the stent and is sized to receive the ring portion **32** of the valve member **30**. In one preferred embodiment, the ring is configured to snap fit into the groove, as seen in FIG. **9**B. In another variation, the ring is made of a shape memory material configured to expand after deployment in the body. In this variation, the ring is configured to radially expand for securely anchoring itself within the groove.

With reference now to FIG. **10**, yet another alternative embodiment of a component prosthetic valve **10**G is illustrated wherein the valve member **30** is configured for threadable engagement with an anchoring member or stent **100**. In this embodiment, the stent is provided on one end with a threaded region **102** along an inner wall configured for receiving a threaded flange portion **33** on the valve member **30**. The threaded flange portion is preferably provided along the ring **32** at the base of the valve member. During use, the stent is first deployed in the body channel. The stent may be deployed in a manner wherein the diameter of the threaded region remains substantially constant so as to not affect the threads. In one embodiment, the stent is substantially non-expandable and is delivered into the lumen in its fully expanded condition. This can be achieved by first stretching or dilating the delivery site for receiving the stent. In another embodiment, only the lower portion of the stent is expanded for engaging the tissue. In either embodiment, the valve member is threadably attached to the threaded flange on the stent after the stent has been firmly anchored in the body channel. This attachment means is configured such that the valve member advantageously connects to the stent through rotational movement. Accordingly, longitudinal forces applied to the valve member after implantation will have little or no effect on the integrity of the connection between the stent and valve.

With reference now to FIG. **11**, an alternative prosthetic heart valve **10**H comprises a valve member **30**, an anchoring member or stent **110**, and a locking ring **112**. As before, the stent **110** desirably expands first at the implantation site, after which a conventional valve member **30** couples to the stent through the use of the locking ring **112**. However, the valve member **30** may also be expandable, and the stent **110** can take a variety of forms. In a preferred embodiment, the stent **110** comprises a latticework of balloon-expandable members adapted to be delivered to the implantation site in a collapsed or compressed state, and then expanded from within using a balloon. Of course, a self-expanding stent **110** could also be used, and additional anchoring means of such as exterior barbs may be provided to help prevent the stent from migrating after implantation.

A series of tabs or flanges **114** project slightly inwardly from an outflow end of the stent **110**. The flanges **114** are configured to mate with exterior threading **116** on a downwardly-projecting shoulder of the locking ring **112**. The number and configuration of the flanges **114** is selected to avoid interfering with radial expansion of the stent **110**, and also to mate with the threads **116** of the locking ring **112**. Desirably, a series of space-apart flanges **114**, for example eight, evenly spaced around the outflow rim of the stent **110** project inward therefrom a distance of between 1-3 mm.

An inner bore **118** of the locking ring **112** possesses a diameter large enough to pass over the entire valve member **30** except for the base ring **32**, which could be a sewing ring of a conventional heart valve. When coupled together, the locking ring **112** surrounds the valve member **30** and desirably includes an inner ledge that rests on the base ring **32** thereof. The inner diameter of the shoulder having the exterior threading **116** is sized larger than the base ring **32** and extends downwardly into engagement with the flanges **114**. By screwing down the locking ring **112**, the components can be easily and rapidly assembled. After implantation, removal and replacement of the valve member **30** merely requires releasing the locking ring **112** from any tissue ingrowth, unscrewing and removing it, and releasing the valve member **30** from the stent **110** by cutting away any tissue ingrowth therebetween.

FIGS. **12**A and **12**B illustrate another prosthetic heart valve **10**I of the present invention having an expandable anchoring member or stent **120** coupled to a valve member **30**. Much like the valve **10**A of FIGS. **3** and **4**, the outflow end of the stent **120** exhibits a series of spaced-apart tabs **122** that curl around the base ring **32** of the valve member **30**. In this embodiment, the stent **120** is a straight tube, and there are fewer tabs **122** (e.g., eight) than there are tines **46** in the valve **10**A. The tabs **122** may be bent using an auxiliary tool (not shown), or may possess a property permitting autonomous bending, such as temperature-induced movement.

FIGS. **12**C and **12**D are sectional views through one side of the prosthetic heart valve **10**I of FIG. **12**B schematically illustrating an exemplary tool that may be used to bend the tabs **122** on the outflow end of the stent **120** around the base ring **32** of the valve member **30**. It should be noted that the section is taken radially through one side of the system, and the tool will typically be annular or at least peripherally arranged to bend each one of the tabs **122**. The tool comprises a forming member **124** having a forming surface **125**. The forming member **124** slides within and relative to an outer anvil **126** having an inwardly angled portion **128** that directly surrounds and engages each of the tabs **122**. The forming surface **125** is curved such that axial displacement of the forming member **124** in the direction shown in FIG. **12**C curls each of the tabs **122** inward to the shape of FIG. **12**D. In this embodiment, the tabs **122** wrap over the top of and restrain the base ring **32**. In other embodiments, the tool may be used to bend prongs so that they pierce the base ring **32**. It should be noted that the outer anvil **126** is primarily used for centering purposes to guide the forming member **124** toward the tabs **122**.

FIGS. **13**A and **13**B illustrate another embodiment of a prosthetic valve **10**J having multiple components joined together. An anchoring member or stent **130** includes a plurality of tangs or flanges **132** on an outflow end. A valve member **30** seats adjacent the outflow end of the stent **130**, and a fixation ring **134** extends therearound. Additionally, a plurality of tabs **136** project downward from the fixation ring **34**. Although not shown, the tabs **136** enable the fixation ring **34** to be coupled to the base ring **32** of the valve member **30** by mechanically bending the tabs, or configuring the tabs to curl upon reaching a certain temperature. As seen in FIG. **13**B, the flanges **132** extend around the outside of the fixation ring **134** and bend around the upper or outflow end thereof. Again, this can be accomplished using an auxiliary tool or through temperature-induced movement. Alternatively, the flanges **132** may be formed of a resilient polymer or metal having the shape seen in FIG. **13**B such that they can be flexed outward around the fixation ring **134** and then snapped back into place to secure the ring around the valve member **30**. Although not shown, the interior of the fixation ring **134** is desirably contoured to mate with the base ring **32** of the valve member **30**. The fixation ring **134** can be made of any number of materials, including rigid, flexible, metallic, polymer, bioabsorbable, etc. One preferred configuration is a Teflon ring coated with anti-thrombogenic or anti-microbial compositions.

FIG. **14**A illustrates a still further prosthetic heart valve **10**K having an expandable anchoring member or stent **140**, a valve member **30**, and a wireform-shaped adapter **142**. The stent **140** and valve member **30** have been previously described. The adapter **142** has a shape similar to a so-called "wireform" used in the internal construction of many prior art bioprosthetic tissue valves. Indeed, the valve member **30** is desirably a Carpentier-Edwards PERIMOUNT Magna® Aortic Heart Valve made by Edwards Lifesciences, and including therewithin an Elgiloy wireform. The adapter **142** may be formed of biocompatible polymers or metals, preferably an alloy such as Nitinol.

The adapter **142** carries a plurality of securing tabs **144**, **146**. In the illustrated embodiment, three lower securing tabs **144** are located at the apex of the three cusps of the wireform-shape, and two upper securing tabs **146** are located at each of the upstanding commissures of the wireform-shape, for a total of six at the commissures. FIG. **14**B is a detailed illustration of the assembly of the stent **140**, valve member **30**, and adapter **142**. The base ring **32** of the valve member **30** seats on or just within the outflow end of the stent **140**, and the adapter **142** fits over the valve member and couples to it, as well as to the stent. In this regard, the cusps of the adapter **142** seat on or slightly outside the base ring **32** with the commissures surrounding and conforming to the commissures of the valve member **30**. The cusp securing tabs **144** bend up over the base ring **32** and down into engagement with the stent **140**. The two securing tabs **146** at each commissure of the adapter **142** bend or wrap around the corresponding valve member commissure.

Again, a supplemental tool may be used to accomplish the bending of the securing members **144**, **146**, or they may exhibit temperature-changing properties. In the illustrated embodiment, the securing tabs **144**, **146** are malleable, though other configurations are within the scope of the invention. For example, the lower securing tabs **144** may be barbs or tangs which pierce the base ring **32** and hook around the stent **140**, while the upper securing tabs **146** may be resilient straps that wrap around each one of the commissures of the valve member **30**.

To further secure the valve member **30** to the stent **140**, the stent includes a plurality of upstanding barbs **147** comprising spaced apart posts having teeth **140**. The adapter **142** possesses a plurality of outwardly projecting brackets **149** defining slots therethrough. As seen in FIG. **14**B, the barbs **147** pass through the base ring **32** and through the slots of the brackets **149** in the adapter **142**. The teeth **148** prevent removal of the barbs **147** from the slots. In this way, the stent **140** and adapter **142** are securely connected together, sandwiching the valve member **30** therebetween.

Another possibility is that the securing tabs **144**, **146** are not initially carried by the adapter **142**, but instead are added after the assembly of the three components. For instance, staples or even sutures may be used after the valve member **30** seats on the stent **140**, and the adapter **142** is lowered around the valve member. Even if sutures are used, the time required relative to a conventional sewing operation is greatly reduced. Moreover, the structural support and anchoring properties of the wireform-shaped adapter **142** greatly enhances the overall integrity of the assembly. In this regard, securing tabs such as those shown may be placed more continuously around the adapter **142** so as to provide more uniform contact with the valve member **30**. One possible configuration is a series of small hooks or brackets extending along the undulating adapter **142** that loop over the corresponding undulating shape on the valve member **30**. The valve member **30** is therefore restrained from upward movement relative to the adapter simply by lowering the adapter **142** over the valve member. In such an arrangement, only the lower securing members need be actively attached, such as by causing their shape to change and bend into engagement with the stent **140**, as seen in FIG. **14**B.

A further prosthetic valve embodiment **10**L seen in FIG. **15**A includes an expandable anchoring member or stent **150** and a valve member **30**. A plurality of fixation straps **152** ring the outflow end of the stent **150**. Four such straps **152** are shown, but more or less made be utilized. For example, three straps extending farther around the periphery of the outflow end of the stent **150** may be substituted. Conversely, four or more straps that overlap one another may be used.

FIG. **15**B illustrates the valve member **30** seated on top of the stent **150** with one of the straps **152** securing the two components together. Straps **152** may be attached at both of their ends to the stent **150**, and may comprise a resilient biocompatible material that stretches over the base ring **32** of the valve member **30**. Alternatively, the straps may be bent or folded over the base ring. In one variation, one end of each strap **152** may be initially free, and after the strap is looped over the base ring **32** is then attached to the stent **150**, somewhat like a belt configuration. The straps **152** may be formed of a variety of materials, typically cloth-covered so as to permit tissue ingrowth over a cloth-covered base ring **32** for enhanced long-term anchorage. One possible variation is to incorporate small barbs or Velcro-style hooks in each of the straps **152** so as to gain better purchase on the base ring **32**.

FIGS. **16**A and **16**B illustrate a still further embodiment, wherein the prosthetic heart valve **10**M comprises a valve member **30**, expandable anchoring member or stent **160**, and coupling ring **162**. The coupling ring **162** defines a series of circumferentially-spaced apertures or slots **164** that receive upstanding hooks or latches **166** on the stent **160**. As seen in FIG. **16**B, the coupling ring **162** surrounds the commissures of the valve member **30** and seats on the base ring **32**, and the latches **166** extend through the slots **164** and are secured therein by outwardly directed teeth **168**. In the illustrated embodiment, the latches **166** each comprise a pair of parallel, spaced apart upstanding members, each with an outwardly directed tooth **168**, which may be cammed inward toward one another as they pass through the slots **164**. As the teeth **168** clear the slot **164**, the parallel members resiliently spring outward thus latching the stent **160** to the coupling ring **162**. The coupling ring **162** may further include a plurality of outwardly projecting tabs **172** that are bent or curl around the base ring **32**.

To aid in guiding the latches **166** through the slots **164**, one or more guide members may be used to direct the coupling ring toward the stent such that the slots are aligned with the latch members. For example, in the illustrated embodiment, a plurality of guide filaments **170** are attached to each one of the upstanding latch members and passed through the corresponding slots. FIG. **16**A illustrates the pre-assembled valve **10**M with the guide filaments **170** extending up through each of the slots **164**. The implantation procedure comprises first delivering and expanding the stent **160**, and then advancing the valve member **30** to the position shown in FIG. **16**B. The coupling ring **162** is then parachuted down the array of guide filaments **170**, ultimately facilitating passage of the latches **166** through the slots **164**. The final assembly is seen in FIG. **16**B. in a preferred embodiment, each two guide filaments **170** comprises a strand of a single looped passing through small holes in each of the latch members. Removal of the guide filaments **170** is thus a simple matter of just pulling one of the strands, or severing the loop in between the latch members. Note that guide filaments could be used on any of the embodiments described herein to facilitate coupling of the separate components of the prosthetic heart valves. For example, in another variation, a wireform similar to the embodiment illustrated in FIG. **14**A may also be used with a guiding filament.

The exemplary embodiment shows the latches **166** extending around the outside of the base ring **32** of the valve member **30**. It is entirely feasible, on the other hand, to design the latches **166** to pierce through the base ring **32**. Inclusion of the coupling ring **162** is suggested, because of its washer-like function in holding the assembly together. However, the latches **166** may be designed to pierce through and securely fasten to stent **160** to the base ring **32** without the use of the coupling ring **162**. In this regard, the latches **166** may be configured differently, or more than the number shown may be provided. For example, 4, 6, 8, or more single latch members having a configuration such as shown with a leading sharp point and rearwardly directed barb (much like a fish hook) could fight adequate anchorage through a conventional base ring **32** made of a silicone sponge covered with cloth. Those of skill in the art will understand that there are numerous alternatives available.

The stent **160** in FIGS. **16**A and **16**B has an outflow end that is preferably sized larger than its inflow end. More particularly, the outflow end is flared so as to receive therein the base ring **32** of the valve member **30**. In this way, a larger orifice valve member can be utilized than with a straight tubular stent. The reader is also reminded that at least the flared portion of the stent **160** is desirably provided with a sleeve of Dacron or other such fabric to help prevent paravalvular leaking between the base ring **32** and the surrounding native valve annulus.

With reference to FIGS. **17**A and **17**B, yet another two part prosthetic valve **10**N is configured for rapid deployment in a heart for replacing a defective native valve. In this version, an expandable anchoring member or stent **180** couples to a valve member **30** through the use of a coupling ring **182** in a manner similar to the last-described embodiment. The coupling ring **182** carries a plurality of latches **184** which mate with brackets **186** provided on the stent **180**. In the illustrated embodiment, the latches **184** again comprise a pair of spaced-apart latch members having outwardly directed teeth **188**, and the brackets **186** are simply apertures or slots in material loops that extend outward from the stent **180** adjacent its outflow end. Bringing the three components together, the latches **184** extend through the brackets **186** as seen in FIG. **17**B. To facilitate proper and rapid passage of the latches **184** through the brackets **186**, a plurality of guide filaments **190** loop through the brackets **186** and through holes provided in the latches **184**. Simply parachuting the coupling ring **182** down the filaments **190** aims the latches **184** through the brackets **186**.

At this stage, it is important to note that any of the fixation rings (i.e., locking ring **112**, fixation ring **134**, adapter **142**, coupling ring **162**, or coupling ring **182**) described above could be designed to engage the surrounding tissue (annulus) and provide additional protection again paravalvular leakage. For example, a tissue growth factor or fibrin glue or the like may be coated on the exterior of any of these fixation rings for a better seal. Alternatively, the fixation rings might have an outer rim of fabric for encouraging tissue ingrowth. Moreover, the various fixation rings described and the base ring **32** of the valve member **32** may be constructed as a single component. For example, the base ring **32** could be configured to have slots (or any coupling member) in lieu of a separate fixation ring.

With reference now to FIG. **18**, an alternative expandable anchoring member or stent **200** is illustrated wherein the anchoring member is configured to receive a valve member

30 to form a prosthetic heart valve. As illustrated in FIG. **19**, a portion of the valve member is gripped between inwardly extending members located within the stent. More particularly, the stent **200** comprises a plurality of axial struts **202** connected by a number of rows of circumferential crown-shaped struts **204** to form a generally tubular structure. A lower or inflow end of the stent **200** includes a circumferential row of crown-shaped struts **206** that is larger than the others such that the inflow end of the stent flares outward. The upper rows **204** of circumferential struts define valleys (pointing downward) at the axial struts **202** and peaks (pointing upward) midway between each two adjacent axial struts. As seen from FIG. **18**, therefore, the spaces defined between adjacent axial struts **202** and adjacent rows of circumferential struts **204** are preferably chevron-shaped, pointed upward. Conversely, the lower circumferential row of struts **206** has upper peaks at the axial struts **202** and lower valleys therebetween, resulting in elongated hexagon-shaped spaces between the lower two circumferential rows of struts.

The stent **200** possesses a plurality of prongs that extend inward therefrom to capture the valve member **30**. As seen in FIG. **19**, the base ring **32** of the valve member **30** seats on a plurality of lower prongs **208**. FIG. **18** shows the lower prongs **208** extending inward from the lower row of struts **206** at the valleys between adjacent axial struts **202**. The lower prongs **208** terminate in enlarged heads **210** to prevent damage to the base ring **32**. As seen in FIG. **19**, the lower prongs **208** project inward farther than the expanded to defined by the upper portion of the stent **200**. Additionally, a plurality of upper prongs **212** extend inward from one of the upper rows of circumferential struts **204**. In the illustrated embodiment, there are four rows of circumferential struts **204**, and the upper prongs **212** project inward from the second lowest row. As seen in FIG. **19**, the upper prongs **212** contact the base ring **32** of the valve member **30**. In this manner, the valve member **30** is captured between the lower prongs **208** and upper prongs **212**.

In the illustrated embodiment, the stent **200** includes twelve axial struts **202**, and one of each of the prongs **208**, **212** between each adjacent pair of axial struts, resulting in twelve each of the lower and upper prongs. Of course, the number of prongs could be more or less depending on the configuration of the stent **200**. Further, there may be more than one prong between adjacent pairs of axial struts **202**, or the prongs may be provided only between every other pair. The prongs **208**, **212** may be initially flat within the profile of the surrounding struts to prevent interference with an expansion-balloon. After stent deployment they may be bent inward into the angles shown using a tool (not shown). Alternatively, the balloon wall could be relatively thick and able to withstand puncture by the round heads of the prongs **208**, **212** such that they are at all times biased inward and automatically assume the angles shown after balloon removal.

To deploy the prosthetic heart valve of FIGS. **18** and **19**, the user advances the stent **200** in a collapsed state through the vasculature or a chest port into the target implantation site. Through self-expansion or balloon-expansion, the stent **200** expands into contact with the surrounding valve annulus. The valve member **30** then advances into position adjacent the outflow or upper end of the stent **200**. Desirably, the valve member **30** is a conventional non-expandable design, but could also be expandable, in which case it is then expanded prior to assembly with the stent **200**.

The outer diameter of the base ring **32** of the valve member **30** is sized approximately the same as the inner diameter of the tubular upper portion of the stent **200**. The valve member **30** advances from the outflow end of the stent **200** toward the inflow end until the base ring **32** contacts the circular row of upper prongs **212**. The upper prongs **212** are flexible, hinged, or otherwise capable of being displaced outward by the base ring **32** as the valve member **30** passes. Ultimately, the base ring **32** seats on the circular row of relatively non-flexible lower prongs **28** and the valve member **30** cannot be advanced farther. The spacing between the lower prongs **208** and the upper prongs **212** is such that the upper prongs **212** spring inward at the point that the base ring **32** seats on the lower prongs **208**. The upper prongs **212** may be formed with blunt heads like the lower prongs **208**, or may be straight or even sharp-pointed to pierce the base ring **32** and provided enhanced anchorage. In a preferred embodiment, both the lower prongs **208** and upper prongs **212** possess enlarged, blunt heads such that the base ring **32** is merely trapped between the two sets of prongs.

The design of the stent **200** of FIG. **18** thus enables rapid deployment of a valve member therewithin, as well as positive tactile feedback to the user with valve member **30** is completely installed. Because the base ring **32** is sized closely within the stent **200**, good peripheral sealing is provided. To better enhance sealing, a peripheral skirt or layer of graft material may be added on the interior or exterior of the stent **200**.

With reference to FIG. **20**, another embodiment of a prosthetic heart valve **220** comprises a tubular, expandable anchoring member or stent **222**, a valve member **30**, and an adapter ring **224** for coupling the two components together. The stent **222** and manner of connecting the stent to the valve member **30** is similar to embodiment of FIGS. **3** and **4**, and also the embodiment of FIG. **12**, in that a plurality of tines **226** project upward from the stent **222**. However, instead of the tines **226** piercing or curling around the base ring **32** of the valve member **30**, the tines interact with the adapter ring **224**. In particular, the adapter ring **224** attaches around the lower periphery of the base ring **32**, preferably via a secure stitch line formed during assembly of the valve member **30**. The tines **226** pierce or otherwise engage the adapter ring **224** instead of the base ring **32** to couple the valve member **30** to the stent **222**. The supplemental adapter ring **224** provides an added margin of safety that helps prevent damage to the valve member **30** by the tines **226**. For instance, if the tines **226** are configured to pierce and curl inward, they are farther away from the inner flexible leaflets **36** of the valve member which are susceptible to puncture or tearing.

With reference to FIG. **21**, yet another embodiment of a prosthetic heart valve **230** comprises an anchoring member or stent **232** coupled to a valve member **30** via a plurality of sutures **234**. The components of the valve **230** are shown exploded above a container or jar **236** used to store the components. In this regard, the entire assembly, including the attachment sutures **234**, may be stored together in the jar **236** so as to be ready for deployment. Alternatively, only the stent **232** and valve member **30** may be stored in the jar **236**, and the sutures **234** added just prior to deployment but before the actual operation. Still further, the stent **232** can be stored dry in a sterile container, while the valve member **30** having bioprosthetic leaflets may be stored separately in a suitable preservative fluid such as glutaraldehyde. In any event, details of the prosthetic heart valve **230** will be described below with reference to FIGS. **22**A through **22**C.

FIGS. **22**A through **22**C show the components of the prosthetic heart valve **230** in conjunction with a valve dilator/delivery tube **240**. The usage of the delivery tube **240** will be described below. The stent **232** comprises an expandable, tubular structure formed of a plurality of axial struts **242** joined by a plurality of angled circumferential struts **244**. In this embodiment, there are four rows of circumferential struts **244**, the upper two pointing upward, and the lower to pointing downward. The result is a series of both diamond-shaped and chevron-shaped openings. Three axial bars **246** substitute for the more narrow struts **242** at three evenly-spaced positions around the stent **232**. As seen in the view of FIG. **22**B, the commissures **34** of the valve member **30** align with the axial bars **246**.

With reference now to the sectional view of FIG. **22**C, the stent **232** additionally comprises an inner fixation ring **250** and an outer sealing ring **252**. Both these rings **250**, **252** attach to the struts of the stent **232** independently, or to each other through the struts. For example, a series of sutures (not shown) can be used to join the inner ring **250** and outer ring **252** in a relatively continuous circumferential line around the stent **232**. These rings are desirably made of suture-permeable, typically compressible material such as silicone rubber, or may be rolled up fabric cuffs. In any event, the inner fixation ring **250** couples to the valve member **30**, while the outer sealing ring **252** help prevent leakage around the stent **232**.

As seen in FIG. **22**A, the attachment sutures **234** extend upward within the stent **232** from the inner fixation ring **250**. In this regard, each two strands of the attachment sutures **234** may be defined by looping a single length of suture downward and back upward through the fixation ring **250**. The circular array of sutures **234** then passes through corresponding sectors of the base ring **32** of the valve member **30**. Again, this can be done at the time of valve assembly, just prior to the valve replacement procedure, or after the stent **232** has been implanted. Those of skill in the art will understand the process of lining up the circular array of attachment sutures **234** into the appropriate locations around the base ring **32** to permit the valve member **32** to parachute down the sutures until it contacts the fixation ring **250**.

The entire procedure will now be described in conjunction with use of the valve dilator/delivery tube **240**. As mentioned above, the valve replacement procedures described herein are sometimes done without removing the existing native valve. The annulus and valve leaflets are often heavily calcified, and sometimes provide a serious impediment to passage and implant of a replacement valve, even a valve that is initially quite small and balloon expanded. To help widened the orifice in which the prosthetic valve **230** will be implanted, the delivery tube **240** receives all of the valve components therein and acts as a protective sleeve and dilator. In a preferred embodiment, just the sealing ring **252** extends out of the delivery tube **240** at an inflow or leading end thereof.

First, the attachment sutures **234** are preinstalled within the fixation ring **250** and, while maintaining a non-crossing circular array, are passed through the delivery tube **240** to be accessible out the upper end. The sutures **234** are then passed through the appropriate locations within the base ring **32** of the valve member **30**. Of course, this can be done during fabrication of the prosthetic heart valve **230**, though some structure for maintaining the relative position and orientation of two components is required. In any event, a holder (not shown) attached to the valve member **30** is used to advance the valve member along the array of sutures **234** and within the delivery tube **240**, into the approximate position seen in FIG. **22**A.

When the patient has been prepared, and an access opening to the target implantation site created, the assembly of the prosthetic heart valve **230** within the delivery tube **240** advances into the body. The leading end comprises the sealing ring **252** and an outwardly bulged portion **254** in the delivery tube **240**. For installation in the aortic annulus, the delivery tube **240** advances down the ascending aorta until the stent **232** lines up with the annulus (with the help of radiopaque markers or the like). The outwardly bulged portion **254** in the delivery tube **240** helps open up the calcified annulus. Even if the native valve is resected, sometimes the annulus will shrink a little prior to implant of the valve. The valve dilator/delivery tube **240** thus helps open up the annulus to permit implant of a desired diameter valve. The contour of the bulged portion **254** is relatively smooth, and the material may be Teflon or other such highly lubricated surface so that the tube easily slips through the annulus. A slight back-and-forth movement may be required to fully open the annulus.

At this stage, the delivery tube **250** retracts relative to the stent **232**, through the use of a pusher (not shown) for example, such that the stent **232** may fully expand into the annulus. The stent **232** may be self-expanding and thus be only partially expanded within the delivery tube **240**. When the delivery tube **240** is removed, the stent **232** springs outward into firm engagement with the annulus. Alternatively, a balloon (not shown) may be used to accomplish the final expansion of the stent **232**, which configuration would require a catheter passing through the center of the valve leaflets **34**. If the stent **232** is balloon expandable, consideration must be taken of the continual attachment of the valve to the guide sutures **234**. On the other hand, if the stent **232** is self-expanding, then typically an auxiliary sheath would be provided to hold the stent in the contracted condition.

When the user is satisfied that the stent **232** is properly positioned, the valve member **30** is advanced using the aforementioned holder (not shown). As the valve member **30** advances, care is taken to ensure that the attachment sutures **234** remain untangled and taut. Ultimately, the valve member **30** seats on the fixation ring **250** as seen in FIGS. **22**B and **22**C. At this point, the user ties off and severs the attachment sutures **234** in a conventional manner. The provision of the sealing ring **252** directly adjacent and surrounding the fixation ring **250** greatly enhances the ability of the prosthetic valve **230** to resist paravalvular leaking.

In one advantageous feature, preferred embodiments of the component based prosthetic valves described herein may be used with existing technology. For example, certain stent embodiments may be configured for attachment to sewing rings provided on existing prosthetic valves. In other cases, valve member require only small variations in order to be used with the component based system. Not only will this contribute to a lower price for the final valve, but also learned familiarity to the system for surgeons who might be hesitant to adopt a completely new system.

It will be appreciated by those skilled in the art that embodiments of the present invention provide important new devices and methods wherein a valve may be securely anchored to a body lumen in a quick and efficient manner. Embodiments of the present invention provide a means for implanting a prosthetic valve in a surgical procedure without requiring the surgeon to suture the valve to the tissue. Accordingly, the surgical procedure time is substantially decreased. Furthermore, in addition to providing an anchoring member for the valve, the stent may be used to maintain the native valve in a dilated condition. As a result, it is not necessary for the surgeon to remove the native leaflets, thereby further reducing the procedure time.

It will also be appreciated that the present invention provides an improved system wherein a valve member may be replaced in a more quick and efficient manner. More particularly, it is not necessary to cut any sutures in order to remove the valve. Rather, the valve member may be disconnected from the stent (or other support structure) and a new valve member may be connected in its place. This is an important advantage when using biological tissue valves or other valves having limited design lives. Still further, it will be appreciated that the devices and methods of the present invention may be configured for use in a minimally invasive approach (e.g., through a small incision between the ribs) or in a percutaneous procedure while still remaining within the scope of the invention.

While the invention has been described in its preferred embodiments, it is to be understood that the words which have been used are words of description and not of limitation. Therefore, changes may be made within the appended claims without departing from the true scope of the invention.

What is claimed is:

1. A prosthetic heart valve comprising:

a non-expandable valve member comprising a base ring surrounding an inflow end thereof;

an expandable anchoring member sized to contact and anchor to a heart valve annulus in an expanded state, the expandable anchoring member comprising an expandable, tubular structure formed of a plurality of axial struts joined by a plurality of angled circumferential struts; and

means for coupling the non-expandable valve member to the anchoring member.

2. The prosthetic heart valve of claim **1**, wherein the means for coupling comprises a plurality of sutures.

3. The prosthetic heart valve of claim **1**, wherein the anchoring member comprises a suture-permeable fixation ring attached thereto, wherein the means for coupling comprises sutures looped between the base ring and the fixation ring.

4. The prosthetic heart valve of claim **3**, further comprising an outer sealing ring.

5. The prosthetic heart valve of claim **1**, further including an adapter sized to surround the non-expandable valve member and to engage the anchoring member, to connect the non-expandable valve member and anchoring member.

6. The prosthetic heart valve of claim **5**, wherein the adapter is selected from the group consisting of:

an annular ring; and

a wireform-shaped member.

7. The prosthetic heart valve of claim **5**, wherein the adapter includes a plurality of discrete connectors, and the anchoring member comprises a plurality of mating connectors spaced around a peripheral outflow end thereof, the connectors on the adapter and anchoring member being configured to engage one another by displacing the adapter toward the anchoring member.

8. The prosthetic heart valve of claim **5**, wherein the adapter further includes a plurality of connectors adapted to engage and couple the adapter directly to the base ring.

9. The prosthetic heart valve of claim **1**, wherein the expandable, tubular structure comprises a series of both diamond-shaped and chevron-shaped openings.

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